FSIS DIRECTIVE 5000.1

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

ENFORCEMENT OF REGULATORY REQUIREMENTS IN ESTABLISHMENTS SUBJECT TO THE HACCP SYSTEM REGULATIONS (including regulations on Sanitation SOP's, E. coli Testing and Criteria, and Salmonella Performance Standards)

PART ONE--GENERAL

I. PURPOSE

To further the goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule in July 1996. As amended by that rule, FSIS's regulations require establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur. These regulations are the framework for a modernized approach to inspection that relies less on after-the-fact detection of problems and more on verifying the effectiveness of processes and process controls designed to assure food safety (that is, the establishment's system for assuring food safety).

This directive provides instructions to inspection program personnel for reviewing an establishment's HACCP plan and otherwise enforcing the HACCP system regulations (9 CFR part 417). It also updates previous instructions to inspection program personnel regarding the regulations on Sanitation Standard Operating Procedures (SOP's) (9 CFR part 416). In addition, this directive addresses actions based on noncompliance with the E. coli process control verification requirements in establishments that slaughter cattle, swine, chickens, or turkeys (9 CFR 310.25(a) and 381.94(a)) and the pathogen reduction performance standards for Salmonella in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey (9 CFR 310.25(b) and 381.94(b)).

DISTRIBUTION: Inspection Offices; T/A Inspectors; Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD, Import Offices

Inspection program personnel are to follow the instructions in this directive in every establishment that is subject to the HACCP system regulations and, for enforcement of the E. coli process control verification requirements, in other official establishments as well. For enforcement of the Sanitation SOP regulations in establishments that are not yet subject to the HACCP system regulations, inspection program personnel should continue to follow the instructions in FSIS Directive 11,100.3, Amend 2, "Evaluating, Verifying, and Enforcing Sanitation Standard Operating Procedure Requirements."

II. [Reserved]

III. REASON FOR ISSUANCE

As of late January 1998, 1999, or 2000, depending upon establishment size (see Part Two, Paragraph I.A.), official establishments must comply with HACCP system requirements (part 417) and establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey are subject to the pathogen reduction performance standards for Salmonella (§310.25(b) and 381.94(b)).

FSIS is issuing this directive to--

- o provide instructions for enforcing the HACCP system regulations (Part Two),
- o update the instructions previously issued for enforcing the regulations on Sanitation SOP's (Part Three) and E. coli testing and criteria (Part Four), and
- o address enforcement of the Salmonella pathogen reduction performance standards.

This directive also provides information on how to integrate these activities with other inspection program procedures.

IV. REFERENCES

Regulations: §§ 304.3(c), 310.25 (Attachment 1), 312.6, 381.22(c), 381.94 (Attachment 1), and 381.99, and parts 416 (Attachment 1) and 417 (Attachment 1).

Directives: FSIS Directive 5400.5, "Inspection System Activities" and FSIS Directive, 8800.2, "Performance-Based Inspection System: Overview of Policies and Implementing Procedures"

V. ABBREVIATIONS AND FORMS

CO-- an FSIS compliance officer
CS-- an FSIS circuit supervisor

DO-- the appropriate Field Operations district office
IIC-- the inspector in charge
ISP-- inspection system procedure(s), as compiled in the ISP Guide
NR-- Noncompliance Record, FSIS Form 5400-3
PBIS-- the performance-based inspection system (see FSIS Directive 8800.2)

FSIS Form 5000-1--	HACCP Systems Basic Compliance Checklist (Attachment 2)
FSIS Form 5000-2--	Sanitation SOP's--Basic Compliance Checklist (Attachment 3)
FSIS Form 5000-3--	E. coli Testing--Basic Compliance Checklist (Attachment 4)
FSIS Form 5000-4--	E. coli Testing Checklist--Regulatory Requirements (§ 310.25 or §381.94) Other Compliance/Noncompliance (Attachment 5)

VI. OVERVIEW

This directive addresses the types of determinations that FSIS expects inspection program personnel to make routinely in establishments that are subject to the HACCP system regulations. It specifies the procedures in the ISP that focus on whether or not particular requirements in the regulations on HACCP systems, Sanitation SOP's, E.coli testing and criteria, and Salmonella performance standards are met. When inspection program personnel conducting these procedures determine there has been a failure or failures to comply with regulatory requirements, they are to document their findings on a NR (as instructed in FSIS Directive 5400.5).

In this directive, possible failures to comply with food safety-related regulations are divided into two categories: (1) basic compliance/noncompliance; and (2) compliance/noncompliance with other requirements. This directive does not address the Agency's other consumer protection activities, such as economic adulteration or misbranding. Those requirements remain the subject of procedures in the ISP Guide (see FSIS Directive 5400.5 and attachments and FSIS Directive 8800.2 and attachments). The Agency also is limiting the application of the following FSIS directives to establishments that are not subject to the HACCP system regulations: 5400.1 and 5400.2 (Inspection System Guide and updating procedures); 8800.1 (PBIS implementation); 8800.3 (updating establishment/shift monitoring plans); 8810.1 (plant profile instructions); 6350.1 (trimming, vacuuming, and other carcass interventions); 6540.1 (antimicrobial use of TSP); 7310.4 (foreign particle contamination); 8820.1 (corrective action system); 8821.1 (boneless meat reinspection); 8830.1 (progressive enforcement action); and 11,100.3 (Sanitation SOP requirements).

Basic compliance/non-compliance focuses on establishment failures to institute the systems required by FSIS regulations and includes types of noncompliance for which FSIS has specified the appropriate enforcement action to be initiated by the inspection program personnel who find these failures. For compliance/non-compliance determinations regarding other food safety regulatory requirements, FSIS decisionmaking on how and when to act generally will take into account additional information on establishment performance. This does not, however, limit or otherwise effect other appropriate actions that inspection program personnel take to protect the public health (including the use of official marks and devices to prevent distribution of adulterated products).

PART TWO--HACCP SYSTEMS

I. GENERAL

A. Applicability of Regulations

The HACCP system regulations (part 417) apply in all official establishments as of the following dates:

January 26, 1998, in an establishment with 500 or more employees ("large establishment");

January 25, 1999, in an establishment with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than $2.5 million) ("smaller establishment"); and

January 25, 2000, in an establishment with fewer than 10 employees or annual sales of less than $2.5 million ("very small establishment").

FSIS will begin making compliance determinations pursuant to this directive as of the date the HACCP system regulations apply in a particular establishment.

B. Regulatory Overview

FSIS views a HACCP system as essential in carrying out an establishment's responsibility to comply with regulatory requirements and prevent the distribution of adulterated products. FSIS's position is that failure to develop and implement a HACCP plan that complies with §417.2 or failure to operate in accordance with part 417 requirements may render products produced under those conditions adulterated (pursuant to FMIA sections 8 and 21 or PPIA sections 7 and 14)
(§ 417.2(e)).

Inspection program personnel will perform procedures to verify the adequacy of an establishment's HACCP plan(s) by determining that each plan meets the requirements of part 417 and other applicable food safety regulations (§ 417.8).

FSIS may find an establishment's HACCP system to be inadequate if:

- o the HACCP plan in operation does not meet the requirements in part 417 (§ 417.6(a));
- o establishment personnel are not performing tasks specified in the HACCP plan (§ 417.6(b));
- o the establishment fails to take corrective actions, as required by § 417.3 (§ 417.6(c));
- o records are not maintained (as required in §417.5) (§ 417.6(d)); or
- o adulterated product is produced or shipped (§ 417.6(e)).

C. Terminology

For purposes of the HACCP system regulations:

"corrective action"-- procedures to be followed when a deviation occurs;

"critical control point" (CCP)--a point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level;

"critical limit"-- the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard;

"food safety hazard" or "hazard"-- any biological, chemical, or physical property that may cause a food to be unsafe for human consumption;

"HACCP system"-- the HACCP plan in operation, including the HACCP plan itself;

"preventive measure"-- physical, chemical, or other means that can be used to control an identified food safety hazard;

"process-monitoring instrument"-- an instrument or device used to indicate conditions during processing at a critical control point; and

"responsible establishment official"-- the individual with overall authority on-site or a higher level official of the establishment

(§ 417.1).

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

When the HACCP system regulations first apply to an establishment and as appropriate thereafter, inspection program personnel will perform a procedure (ISP procedure 03A01) to determine whether or not an establishment has complied with the requirements addressed in Paragraph II.B. of this part. (See the basic compliance checklist, FSIS Form 5000-1.)

B. Requirements

1. Hazard analysis and HACCP plan development

a. Initial hazard analysis. The establishment conducted a hazard analysis or had a hazard analysis conducted for it (§ 417.2(a)).

(1) The hazard analysis includes food safety hazards that are reasonably likely to occur in the production process (before, during, and after entry into the establishment) and (when there are any) it identifies the preventive measures the establishment can apply to those food safety hazard(s).

(2) The hazard analysis includes a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.

(3) The hazard analysis identifies the intended use or consumers of finished product(s).

b. Initial plan development

(1) If an establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, the establishment has a written HACCP plan for each of its products (at the time commercial production begins) (§ 417.2(b)(1); § 304.3(c) or § 381.22(c)). (A HACCP plan must be developed by an individual who satisfies the training requirements in § 417.7(b) (§ 417.7(a)(1)); see Paragraph III.B.3.c. of this part.)

(Note: It is possible (though unlikely) that a hazard analysis conducted in accordance with § 417.2(a) will reveal no food safety hazards that are reasonably likely to occur. FSIS is

not aware of any meat or poultry production process that one can say, categorically, poses no likely hazards.)

(2) The establishment conducted validation activities to determine that a HACCP plan is functioning as intended, and the establishment's records--

- o include multiple results that verify the monitoring of CCP's and conformance with critical limits, and
- o after each deviation from a critical limit (if any), demonstrate subsequent results that support the adequacy of corrective action(s) in achieving control at the CCP.

(§§ 417.2(c)(4), 417.3(a)(2), and 417.4(a)(1)).

c. Subsequent analysis and plan development

(1) Hazard analysis reassessment. If, after an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists, the establishment reassessed the adequacy of the hazard analysis (§417.4(b)). (Examples of changes that might have such an effect: raw materials or raw materials' source, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution system, or intended use or consumers of finished product.)

(2) New product

(a) Before producing a new product for distribution, the establishment--

- o conducted a hazard analysis (or had a hazard analysis conducted for it), and
- o has an applicable HACCP plan for the product.

(b) If the establishment began distributing a new product more than 90 days ago, it has validated the HACCP plan that covers the new product.

(§ 304.3(c) or § 381.22(c))

2. Contents of HACCP plan(s)

a. Multiple products. If a HACCP plan covers more than one product, the products are all within one of the nine processing categories specified in § 417.2(b)(1) (§ 417.2(b)(2)).

b. Food safety hazard(s). The HACCP plan lists the food safety hazard(s) identified in the hazard analysis (§ 417.2(c)(1)). (These are the food safety hazards that must be controlled for each process.)

Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§417.2(b)(3)).

c. Hazard control

(1) The HACCP plan lists CCP's for each food safety hazard (§ 417.2(c)(2)).

(2) The HACCP plan lists critical limits to be met at each CCP (§ 417.2(c)(3)).

d. Monitoring. The HACCP plan lists the procedures to be used to monitor each CCP and the frequency with which these procedures will be performed (§ 417.2(c)(4)).

e. Corrective actions. The HACCP plan identifies the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2(c)(5)).

f. Verification procedures. The HACCP plan lists the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed (§ 417.2(c)(7)).

3. Recordkeeping. The HACCP plan's recordkeeping system documents the monitoring of CCP's and includes records with the actual values and observations (§ 417.2(c)(6)).

4. Dated signature

a. Acceptance and reassessment. The responsible establishment official has signed and dated the HACCP plan--

- o upon initial acceptance (§ 417.2(d)(1)), and
- o at least annually thereafter upon required plan reassessment (§ 417.4(a)(3))

(§ 417.2(d)(2)(i) and (d)(2)(iii)).

(Note: To determine whether a year has elapsed, use the date on which the HACCP system regulations apply to an establishment (January 26, 1998; January 25, 1999; or January 25, 2000) as day one of the first year.)

b. Modification. If the HACCP plan was modified, the responsible establishment official signed and dated the plan (§ 417.2(d)(2)(ii)).

C. Enforcement Actions

Finding noncompliance with requirement(s) addressed in Paragraph II.B. of this part in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied. Inspection program personnel who determines that an establishment has failed to meet one or more of these requirements is to take the following steps:

1. Advise establishment management orally of the findings on which the intended action is based and (as soon as possible where practicable and by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."

b. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained."

3. Notify the DO of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance,

- o notify the DO (which will assign a CO) and,
- o in conjunction with the CO, develop a case file and take further action as appropriate.

Note: If noncompliance with Paragraph II.B. requirements involves only a failure that the responsible establishment official can cure effectively and immediately (for example, the

responsible establishment official did not sign and/or date the HACCP plan when required), then before taking these steps, inspection program personnel are to provide establishment management with an opportunity to bring the establishment into compliance.

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 03B01 and 02 through 03J01 and 02) to verify the adequacy of an establishment's HACCP plan(s) by making determinations about compliance with regulatory requirements.

PBIS will schedule procedures, selecting either--

- a procedure for reviewing features of a HACCP plan in operation (for example, correlating records with random observation or measurement at a CCP), or
- a procedure for reviewing implementation of a HACCP plan for a particular product.

The objective of these activities is to determine whether, as documented in its records (§ 417.5), the establishment is complying with the requirements for implementation of a HACCP plan, including monitoring, verification, and corrective action requirements (§§ 417.2(c)(4) and (c)(6), 417.3, 417.4(a), and 417.5 and § 304.3(c) or § 381.22(c)), so that FSIS can make determinations about HACCP system adequacy (§ 417.6), including whether the system prevents the distribution of adulterated products that may endanger public health.

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain an adequate HACCP plan, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.) Similarly, finding Listeria monocytogenes in a ready-to-eat product or residues of an animal drug that are not within an applicable tolerance established under the Federal Food, Drug, and Cosmetic Act is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Establishment monitoring

a. The establishment is monitoring CCP's to ensure compliance with critical limits (§ 417.2(c)(4)).

b. Establishment records documenting the monitoring of CCP's include the recording of actual values (in terms of observations and times, temperatures, and/or other quantifiable limits in the HACCP plan) (§§ 417.2(c)(6) and 417.5(a)(3)).

2. Establishment verification

a. The establishment is verifying the implementation of its HACCP plan(s) by performing verification activities (§§ 417.2(c)(7) and 417.4(a)(2)).

b. Establishment records documenting verification activities include:

- but are not limited to, the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained in accordance with §417.5(a)(3).
- the review, prior to shipping product, of the records associated with the production of that product to ensure completeness. Where practicable, this review will be conducted, dated, and signed by an individual who did not produce the record(s).

(§§ 417.4(a)(2) and 417.5(c))

c. If an establishment that slaughters cattle, swine, chickens, or turkeys has substituted an alternative frequency for the frequency of sampling for E. coli specified in § 310.25(a)(2)(iii) or § 381.94(a)(2)(iii), the alternative is an integral part of the establishment's verification procedures (paragraph (a)(2)(iv) of § 310.25 or § 381.94; see Part Four, Paragraph III.B.1.d.).

3. Deviations from critical limits

a. Corrective actions

(1) The HACCP plan assigns responsibility for taking corrective action (by, for example, specifying the establishment personnel who will perform various activities) (§ 417.3(a)).

(2) In response to a deviation from a critical limit for which a HACCP plan identifies the corrective action to be taken, the establishment followed the corrective action procedure(s) in the plan (§§ 417.2(c)(5) and 417.3(a)).

(3) The establishment's records document corrective action taken in response to a deviation from a critical limit, including procedure(s) to--

- o identify and eliminate the cause of the deviation,
- o bring the CCP under control,
- o establish measures to prevent recurrence, and
- o prevent distribution of product adulterated as a result of the deviation.

(§§ 417.3(a) and (c) and 417.5(a)(3))

b. Unforeseen hazards. In response to a deviation from a critical limit that a HACCP plan does not cover with a specific corrective action, the establishment's records document procedures used to segregate and hold affected product, at least until the establishment--

- o performed a review to determine the acceptability of affected product for distribution, and
- o when necessary, took action to ensure that product adulterated as a result of the deviation would not be distributed

(§§ 417.3(b) and (c) and 417.5(a)(3))

4. Plan reassessment and modification

a. Reassessment

(1) If a deviation that is not covered by a corrective action specified in a HACCP plan occurred, or another unforeseen hazard arose, the establishment reassessed the HACCP plan (§ 417.3(b)(4)).

(2) If a raw meat product or raw poultry product tested positive for Salmonella at a rate exceeding the applicable performance standard (in Table 2 of § 310.25(b)(1) or § 381.94(b)(1)) on the second consecutive series of FSIS tests for that product, the establishment reassessed the HACCP plan for that product (paragraph (b)(3)(ii) of § 310.25 or § 381.94).

(3) If there was a change that could affect the hazard analysis or alter a HACCP plan, the establishment reassessed the HACCP plan (§ 417.4(a)(3)).

b. Modification. If a plan reassessment revealed that a HACCP plan no longer meets the requirements in § 417.2(c), the establishment modified the HACCP plan (§ 417.4(a)(3)).

c. Training. The individual who performed the reassessment or modification of a HACCP plan meets the training requirements in § 417.7(b) (§§ 417.3(b)(4), 417.4(a)(3), and 417.7(a)(2)).

5. Records

a. HACCP plan support. Establishment records--

- document the decisionmaking associated with the selection and development of CCP's and critical limits, including references to the basis (scientific or technical and/or regulation(s)) for each, and
- support the monitoring and verification procedures that the establishment has selected and the frequency with which the establishment conducts those procedures

(§ 417.5(a)(2))

b. Product identification. Establishment records document slaughter production lot, product code(s), product name, or other identifier (§ 417.5(a)(3)).

c. Authentication. Each entry on a record maintained under a HACCP plan--

- o is made at the time the specific event occurs,
- o includes the date and time that the entry was recorded, and
- o is signed or initialed by the establishment employee who made the entry

(§ 417.5(b))

(Note: Any other record required by § 417.5(a)(3) must include the date on which the record was made.)

d. Data integrity. The establishment has implemented controls to ensure data integrity for HACCP plan records maintained on computers (if any) (§ 417.5(d)).

e. Records review. Prior to shipping a product for distribution, the establishment's review of the records associated with the product's production (to ensure completeness) includes--

- o a determination that all critical limits were met, and
- o when appropriate, a determination that the establishment took corrective action(s), including the proper disposition of product

(§ 417.5(c))

(Note: Where practicable, an individual who did not produce the records must conduct, date, and sign this review.)

f. Retention and availability

(1) The establishment retains records required by § 417.5(a)(3) for at least the following period(s):

- o 1 year for slaughter activities and for refrigerated product;
- o 2 years for product that is frozen, preserved, or shelf-stable

(§ 417.5(e)(1)).

(2) Records required by § 417.5(a)(3):

- o are on-site for at least 6 months, and
- o are available within 24 hours of an FSIS employee's request if stored off-site after 6 months

(§ 417.5(e)(2))

(Remember, the specific retention period and location requirements do not apply until the date on which an establishment must comply with the HACCP system regulations.)

C. Enforcement Actions

1. Finding noncompliance with requirements addressed in Paragraph III.B. of this part in and of itself supports the withholding of inspection only when:

- o inspection program personnel have documented that a HACCP system did not prevent the production and distribution of adulterated product (and not including economic adulteration), and
- o the violations include failures to comply with requirements for monitoring of CCP's, to respond to deviations from critical limits, and to document verification and review of production records.

Under these circumstances, the Inspection program personnel should take the same steps as in cases of basic noncompliance (see Paragraph II.C.).

2. In other situations, the Inspection program personnel is to--

- o take official control action as appropriate,
- o advise establishment management by providing a copy of the NR that documents the noncompliance finding(s),
- o review and verify documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5), and
- o decide whether the establishment's noncompliance history warrants the involvement of a CO, and if so, seek CO involvement through the DO, participate with the CO in the

development of a case file, and take further action as appropriate.

PART THREE--SANITATION SOP'S

I. GENERAL

A. Applicability of Regulations

The Sanitation SOP regulations (part 416) apply in all official establishments.

B. Regulatory Overview

FSIS views Sanitation SOP's as essential to operating and maintaining an establishment in accordance with sanitary practices to prevent the distribution of adulterated products. Failure to comply with part 416 requirements may result in an FSIS determination that the conditions in an establishment are such that livestock product or poultry product is adulterated (because it is unsound, unhealthful, unwholesome, or otherwise unfit for human food or has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health).

Inspection program personnel will perform procedures to verify the adequacy and effectiveness of an establishment's Sanitation SOP's (including the procedures specified in the Sanitation SOP's) by determining that they meet part 416 requirements (§ 416.17).

C. Terminology

As used in this directive:

"pre-operational procedures" refers to the procedures in an establishment's Sanitation SOP's that the establishment is to conduct daily before it begins operations; and

"during-operations procedures" refers to the procedures in an establishment's Sanitation SOP's that the establishment is to conduct daily during its operations.

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

As appropriate, inspection program personnel will perform a procedure (ISP procedure 01A01) to determine whether or not an establishment has complied with the requirements addressed in Paragraph II.B. of this part (basic compliance checks). (See the basic compliance checklist, FSIS Form 5000-2.)

B. Requirements

1. Sanitation SOP's

a. The establishment has written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s) (§ 416.12(a)). (These procedures must be sufficient to prevent direct contamination or adulteration of product(s); see Paragraph III.B.2. of this part.)

b. The Sanitation SOP's identify which of the procedures are pre-operational procedures (§ 416.12(c)).

c. The pre-operational procedures address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils (§ 416.12(c)).

d. The Sanitation SOP's specify the frequency with which the establishment will conduct each procedure (§ 416.12(d)).

e. The Sanitation SOP's identify the establishment employee or employees responsible for implementing and maintaining specified procedures (§ 416.12(d)).

2. Recordkeeping. The establishment has identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOP's and any corrective actions taken (§ 416.16(a)).

3. Dated signature. The individual with overall authority on-site or a higher level official of the establishment has signed and dated the Sanitation SOP's

- upon initial implementation, and
- upon any modification

(§ 416.12(b)).

C. Enforcement Actions

Finding noncompliance with requirement(s) addressed in Paragraph II.B. of this part in and of itself supports the withholding of inspection to prevent the production of products until the failure is remedied. Inspection program personnel who determine that an establishment has failed to meet one or more of these requirements is to take the following steps

1. Advise establishment management orally of the decision to withhold inspection and (as soon as possible and where practicable by the end of his or her tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. a. Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."

b. Identify all possibly adulterated livestock and/or poultry products as "U.S. Retained."

c. Identify violative equipment, utensil(s), room(s), or compartment(s) as "U.S. Rejected."

3. Notify the DO of the action(s) taken and, if the establishment does not initiate action immediately to bring itself into compliance

- o notify the DO (which will assign a CO), and,
- o in conjunction with the CO, develop a case file and take further action as appropriate.

Note: If noncompliance with Paragraph II.B. requirements involves only the failure of the individual with overall authority on-site, or a higher level official of the establishment, to sign and/or date the Sanitation SOP's, then before taking these steps, are to provide establishment management with an opportunity to bring the establishment into compliance.

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform procedures (ISP procedures 01B01 and 02 and 01C01 and 02, to verify the adequacy and effectiveness of an establishment's Sanitation SOP's (including the procedures specified in the Sanitation SOP's) by making determinations about compliance with § 416.11 through § 416.16 requirements.

PBIS will schedule procedures, selecting either

- o a records procedure for reviewing the Sanitation SOP's themselves and the daily documentation of the establishment's implementation of those procedures and required corrective actions, or
- o a procedure for direct observation of the establishment's implementation of Sanitation SOP procedures and required

corrective actions, assessment of sanitary conditions, and review of related records.

The objective of these activities is to determine whether, as documented in the establishment's records (§ 416.16), an establishment is complying with the requirements for

- o implementation of Sanitation SOP's, including monitoring of implementation (§ 416.13),
- o routine evaluation of the effectiveness of Sanitation SOP's (§§ 416.12(a) and 416.14), and
- o taking corrective action(s) (§ 416.15).

In addition, for products covered by Salmonella performance standards (§§ 310.25(b)(1) and 381.94(b)(1)), noncompliance with the standard may constitute failure to maintain sanitary conditions, which would result in the suspension of inspection services (paragraph (b)(3)(iii) of § 310.25 or § 381.94). (The DO will provide further information and instructions on a case-by-case basis.)

B. Requirements

The particular ISP procedure may focus on one or more of the requirements addressed in this Paragraph III.B.

1. Sanitation SOP implementation

a. The establishment conducts pre-operational procedures before it begins operations (§ 416.13(a)).

b. The establishment conducts during-operations procedures at the frequencies specified in its Sanitation SOP's (§ 416.13(b)).

c. The establishment monitors daily the implementation of procedures in its Sanitation SOP's (§ 416.13(c)).

2. Corrective actions. When (as determined by the establishment or by FSIS) the establishment's Sanitation SOP's--or the procedures specified therein or their implementation or maintenance--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to

- o ensure the appropriate disposition of products that may be contaminated,

- o restore sanitary conditions, and
- o prevent recurrence of direct product contamination or adulteration, including appropriate reevaluation and modification of Sanitation SOP procedure(s) or appropriate improvements in the execution of Sanitation SOP procedure(s)

(§ 416.15).

3. Sanitation SOP effectiveness

a. The establishment's Sanitation SOP's are sufficient to prevent direct contamination or adulteration of product(s) (§ 416.12(a)).

b. The establishment

- o routinely evaluates the effectiveness of the procedures in its Sanitation SOP's in preventing direct contamination or product adulteration, and
- o revises the procedures in its Sanitation SOP's when necessary to keep them effective and current with respect to changes in its facilities, equipment, utensils, operations, or personnel

(§ 416.14)

4. Records

a. Daily documentation. The establishment's daily records document

- o implementation of its Sanitation SOP's,
- o monitoring of its Sanitation SOP's, and
- o corrective actions taken (if any)

(§ 416.16(a)).

b. Authentication. The establishment's records are initialed and dated by the establishment employee identified in the Sanitation SOP's as responsible for implementing and monitoring specified procedure(s) (§ 416.16(a)).

c. Data integrity. The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any) (§ 416.16(b)).

d. Retention and availability

(1) The establishment retains records required by part 416 for at least 6 months.

(2) Records required by part 416

- o are on-site for at least 48 hours, and
- o are available within 24 hours of an FSIS employee's request if stored off-site after 48 hours.

(§ 416.16(c))

C. Enforcement Actions

1. Finding noncompliance with requirements addressed in Paragraph III.B. of this part in and of itself supports the withholding of inspection when inspection program personnel have repeatedly documented that an establishment's Sanitation SOP's did not prevent the same type of direct contamination or adulteration of product(s) and, hence, the violations include failure to comply with requirements for corrective actions that prevent recurrence of direct product contamination or adulteration by appropriate reevaluation and modification (maintenance) or appropriate improvements in the execution of Sanitation SOP procedure(s).

Under these circumstances, inspection program personnel should take the same steps as in cases of basic noncompliance (see Paragraph II.C.).

2. In other situations, the IIC is to

- o take official control action as appropriate,
- o advise establishment management by providing a copy of the NR that documents the noncompliance finding(s),

- o review and verify documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5), and

- o decide whether the establishment's noncompliance history warrants the involvement of a CO, and if so, seek CO involvement through the DO, participate with the CO in the development of a case file, and take further action as appropriate.

PART FOUR--E. COLI TESTING AND CRITERIA

I. GENERAL

A. Applicability of Regulations

The E. coli regulations (§§ 310.25(a) and 381.94(a)) apply in any official establishment that slaughters any market class of cattle, swine, chickens, or turkeys.

B. Regulatory Overview

FSIS regulations require E. coli testing as an ongoing, objective process control indicator for fecal contamination. To evaluate the results, FSIS is establishing performance criteria to reflect the prevalence and levels of E. coli on carcasses produced nationwide. FSIS intends these criteria as an initial basis for using microbial testing to evaluate the adequacy of establishment process controls.

There currently are performance criteria for evaluating the results of E. coli testing of--

- o cattle and swine, when samples are collected by excising (§ 310.25(a)(5)(i), Table 1), and

- o chickens (§ 381.94(a)(5)(i), Table 1).

E. coli performance criteria are not regulatory standards. Test results that do not meet applicable criteria indicate that an establishment may not be maintaining process controls sufficient to prevent fecal contamination (paragraph (a)(6) of §§ 310.25 and 381.94)).

Until FSIS establishes performance criteria for evaluating the results, establishments testing cattle and swine that collect samples by sponging carcasses and establishments testing turkeys must use statistical process control techniques (paragraph (a)(5)(ii) of §§ 310.25 and 381.94). (Statistical process control involves initial data evaluation to determine process capability -- the typical process performance level or baseline level-- and then checking subsequent data to see whether they are consistent with the baseline

level to ensure the process is in control and variations are within normal and acceptable limits. Statistical process control techniques are used to check for unreasonably high results, trends, etc. and to look for and correct problems in a process.)

Inspection program personnel will perform a procedure to determine whether or not an establishment is complying with § 325.10(a) or § 381.94(a).

C. Terminology

For purposes of the E. coli regulations, "E. coli" is Escherichia coli Biotype I (§ 310.25(a)(1) or § 381.94(a)(1)).

II. BASIC COMPLIANCE/NONCOMPLIANCE

A. General

As appropriate, inspection program personnel will perform a procedure (ISP procedure 05A01) to determine whether or not an establishment has complied with the requirements set out in Paragraph II.B. of this part. (See the basic compliance checklist, FSIS Form 5000-3).

B. Requirements

1. Sampling procedures

a. The establishment has written procedures for collecting samples for E. coli testing.

b. The establishment's procedures identify the establishment employee(s) designated to collect samples for E. coli testing.

c. The establishment's procedures address

- the location(s) of sampling,
- how sampling randomness is achieved, and
- handling of samples to ensure sample integrity.

(Paragraph (a)(2)(i) of § 310.25 or § 381.94)

2. Sample collection. The establishment collects samples for E. coli testing (paragraph (a)(1) of § 310.25 or § 381.94). (Note: An establishment that slaughters more than one type of livestock or poultry or slaughters both livestock and poultry must test for E. coli in the type that it slaughters in the greatest number.)

3. Recordkeeping. The establishment records the analytical results of E. coli tests on a process control chart or table (paragraphs (a)(1)(iii) and (a)(4) of § 310.25 or § 381.94).

III. COMPLIANCE/NONCOMPLIANCE--OTHER REQUIREMENTS

A. General

Inspection program personnel will perform a procedure (ISP procedure 05A02) for making determinations about compliance with the requirements addressed in Paragraph III.B. of this part. (See the other compliance/noncompliance checklist, FSIS Form 5000-4).

When PBIS schedules the procedure, inspection program personnel will review sample collection procedures, observe collection, and/or review records of test results.

The objective of these activities is to determine whether or not an establishment is complying with the requirements for

- collecting and analyzing samples for E. coli (paragraphs (a)(1)(i), (a)(1)(ii), (a)(2)(ii) through (a)(2)(v), and (a)(3) of § 310.25 or § 381.94), and
- recording E. coli test results (paragraph (a)(4) of § 310.25 or § 381.94,

and whether the establishment is evaluating test results (paragraph (a)(5) of § 310.25 or § 381.94).

B. Requirements

1. Sample collection

a. The establishment collects samples from the type of livestock or poultry that it slaughters in the greatest number (paragraph (a)(1) of § 310.25 or § 381.94).

b. The establishment selects carcasses randomly (paragraphs (a)(1)(i), (a)(2)(i), and (a)(2)(ii) of § 310.25 or § 381.94). In particular, the technique in the establishment's procedures should achieve randomness, when the establishment follows its collection procedures.

c. The establishment collects samples

- at the required location in the process, and
- by the procedure specified in the regulations.

(paragraph (a)(2)(ii) of § 310.25 or § 381.94)

d. The establishment collects samples at the required frequency (paragraph (a)(1)(i) and paragraph (a)(2)(iii), (a)(2)(iv), or (a)(2)(v) of § 310.25 or § 381.94). Either

- o the establishment collects samples at the frequency specified in paragraph (a)(2)(iii) or, in a very low volume establishment, paragraph (a)(2)(v); or
- o if the establishment has substituted an alternative frequency for the frequency specified in paragraph (a)(2)(iii)--
  - (1) the alternative is an integral part of the verification procedures for a validated HACCP plan (see Part Two, Paragraph III.B.1.b.), and
  - (2) FSIS has not determined (and so notified the establishment in writing) that the alternative frequency is inadequate to verify the effectiveness of its processing controls.

(paragraph (a)(2)(iv) of § 310.25 or § 381.94)

e. Is there a reason, other than one or more specific points noted above, to question the integrity of the samples collected by the establishment, or is there other evidence indicating that the results obtained by the establishment may be inaccurate or unreliable for purposes of § 310.25(a) or § 381.94(a)?

In particular, does available information suggest that the establishment's written procedures and/or its practices are inadequate to ensure proper handling in collecting, storing, and transporting samples (for example, failure to use aseptic techniques when collecting samples; improper identification of samples; improper refrigeration of samples; prolonged holding of samples before shipment to a laboratory) or that the carcasses tested were treated differently than other carcasses?

(Remember, FSIS's "Guidelines for E. coli Testing for Process Control Verification in Raw Meat and Poultry" is guidance--not regulatory requirements.)

2. Sample analysis. The establishment obtains test results in accordance with the sample analysis requirements (paragraphs (a)(1)(ii) and (a)(3) of § 310.25 or § 381.94).
(Note: Only address this point when records or other information on analytical methodology is available.)

3. Test results

a. The establishment records the results of all E. coli testing on a process control chart or table that shows

- o at least the most recent 13 test results,
- o in terms of cfu/cm^2 of surface area sponged or excised or cfu/ml of rinse fluid by type of animal slaughtered

(paragraph (a)(4) of § 310.25 or § 381.94)

b. The establishment uses the results of E. coli testing, as follows:

- o when Table 1 does not include applicable m/M criteria, the establishment uses a statistical process control technique (charting or plotting the results over time) to determine what variation in test results is within normal limits;
- o when Table 1 includes applicable m/M criteria, the establishment determines whether it is operating within these criteria

(paragraph (a)(5) of § 310.25 or § 381.94)

c. The establishment retains records of test results for 12 months (paragraph (a)(4) of § 310.25 or § 381.94). (Note: The testing requirement has applied since January 25, 1997. However, under the frequency rule for very low volume establishments, no sampling was required until the first full week of operation after June 1, 1997.)

IV. ENFORCEMENT ACTIONS

A. General

When FSIS finds that an establishment is not complying with one or more provisions of § 310.25(a)(1) through (a)(4) or proceedings (paragraph (a)(7) of § 310.25 or § 381.94). Inspection program personnel initiate this process by notifying an establishment that they have determined the establishment is not complying with provision(s) of paragraph (a)(1), (a)(2), (a)(3), and/or (a)(4) of § 310.25 or § 381.94.

Test results that do not meet applicable m/M criteria (Table 1, paragraph (a)(5) of § 310.25 or § 381.94) indicate that an establishment may not be maintaining process controls

sufficient to prevent fecal contamination (paragraph (a)(6) of § 310.25 or § 381.94). In such situations, FSIS will take further action as appropriate to ensure that applicable provisions of the law are met. The IIC provides the DO with the information needed to determine whether and what further action (if any) to take.

B. Actions

1. Inspection program personnel who determines that an establishment has failed to meet one or more of the requirements addressed in Paragraph II.B. or Paragraph III.B. is to advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of the tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).

2. If an IIC finds noncompliance with provision(s) of paragraph (a)(1), (a)(2), (a)(3), and/or (a)(4) of § 310.25 or § 381.94 and the establishment does not initiate action immediately to bring itself into compliance

- notify the DO (which will assign a CO), and,
- in conjunction with the CO, develop a case file and take further action as appropriate.

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Deputy Administrator
Office of Policy, Program Development
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§ **310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.**

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters cattle and/or swine shall test for Escherichia coli Biotype 1 (E. coli). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) Sample collection. The establishment shall collect samples from all chilled swine or cattle carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples shall be collected by either sponging or excising tissue from three sites on the selected carcass. On cattle carcasses, establishments shall sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments shall take samples by sponging from inside the flank, inside the brisket, and inside the rump; on swine carcasses, establishments shall sponge or excise tissue from the ham, belly and jowl areas.[1]

[1]A copy of FSIS's "Guidelines for E. coli Testing for Process Control verification in Cattle and Swine Slaughter Establishments" is available for inspection in the FSIS Docket Room.

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the volume of production at the following rates:
Cattle: 1 test per 300 carcasses, but at a minimum one sample each week of operation.
Swine: 1 test per 1000 carcasses, but at a minimum one sample each week of operation.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and, (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 20,000 swine, or a combination of cattle and swine not exceeding 6,000 cattle and 20,000 total of both types. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by

[2]A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for evaluation of test results.

(i) An establishment excising samples from carcasses is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1 - EVALUATION OF E. coli TEST RESULTS

Type of Livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	negative	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm^2 carcass surface area.

(ii) Establishments sponging carcasses shall evaluate E. coli test results using statistical process control techniques.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; Salmonella.

(1) Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

§ 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; E. coli testing.

[3] A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(1) Each official establishment that slaughters poultry shall test for Escherichia coli Biotype I (E. coli). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) Sample collection. Samples shall be collected by taking a whole bird from the end of the chilling process, after the drip line, and rinsing it in an amount of buffer appropriate to the type of bird being tested. If the bird is boned before chilling (hot boned poultry), the sample shall be taken from the end of the slaughter line instead of the end of the drip line.[1]

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.
Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation

[1]A copy of FSIS's "Sampling Technique for E. coli in Raw Meat and Poultry for Process Control Verification" is available for inspection in the FSIS Docket Room.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against

[2]A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be [2] A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for Evaluation of test results. An establishment is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1 - EVALUATION OF E. coli TEST RESULTS

Types of Poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Chickens	100 CFU/ml	1,000 CFU/ml	13	3
Turkeys	N.A.[a]	N.A.	N.A.	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.

(ii) For types of poultry appearing in paragraph (a)(5)(i) Table 1 of this section that do not have m/M criteria, establishments shall evaluate E. coli test results using statistical process control techniques.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) Failure to test and record. Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; Salmonella.

(1) Raw poultry product performance standards for Salmonella.

(i) An establishment's raw poultry products, when sampled and tested by FSIS for Salmonella as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers	20.0% [b]	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

PART 416--SANITATION

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;
(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;
(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter--all species.

(ii) Raw product--ground.

(iii) Raw product--not ground.

(iv) Thermally processed--commercially sterile.

(v) Not heat treated--shelf stable.

(vi) Heat treated--shelf stable.

(vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment: and,

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in

accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;

(d) HACCP records are not being maintained as required in § 417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency Verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

FSIS DIRECTIVE 5000.1
Attachment 2

U.S. DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
HACCP SYSTEMS -- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS
PRODUCTS COVERED BY PROCESS		
IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Two, Paragraph II.B.

	REQUIREMENT	YES(✓)
1. HAZARD ANALYSIS AND HACCP PLAN DEVELOPMENT	**INITIAL HAZARD ANALYSIS** § 417.2 The establishment has not conducted a hazard analysis or had a hazard analysis conducted for it.	
	The hazard analysis does not include food safety hazards that are reasonably likely to occur in the production process, or	
	does not identify the preventive measures the establishment can apply to those food safety hazard (s)	
	The hazard analysis does not include a flow chart that describes (diagrams) the steps of each process and product flow in the establishment.	
	The hazard analysis does not identify the intended use or consumers of finished product (s).	
	Initial plan development § 417.2 (c) (4), § 417.3 (a) (2), and § 417.4(a)(1)) The establishment's hazard analysis revealed one or more food safety hazards that are reasonably likely to occur, and the establishment does not have a written HACCP plan for each of its products § 417.2 (b) (1); § 304.3 (c) or § 381.22 (c)).	
	The establishment has not conducted validation activities to determine that a HACCP plan is functioning as intended. The establishment's records do not include multiple results that verify the monitoring of CCP's and conformance with critical limits, or	
	after a deviation from a critical limit (if any), subsequent results that support the adequacy of corrective action (s) in achieving control at the CCP.	
	SUBSEQUENT ANALYSIS AND PLAN DEVELOPMENT HAZARD ANALYSIS REASSESSMENT After an establishment's hazard analysis revealed no food safety hazards that are reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists, the establishment did not reassess the adequacy of the hazard analysis (§ 417.24 (b)).	
	NEW PRODUCT (§ 304.3 (c) or § 382.22 (c)) (1) Before producing new product for distribution, the establishment did not conduct a hazard analysis (or have a hazard analysis conducted for it), or	
	did not have an applicable HACCP plan for the product.	
	(2) The establishment began distributing a new product more than 90 days ago, and it has not validated the HACCP plan that covers the new product.	

FSIS FORM 5000-1 (9/97)

FSIS Directive 5000.1
Attachment 2

	REQUIREMENT	YES (✓)
2. CONTENTS OF HACCP PLAN(S)	**MULTIPLE PRODUCTS** A HACCP plan covers more than one product and the products are not all within one of the nine processing categories specified in § 417.2 (b) (1) § 417.2 (b) (2).	
	FOOD SAFETY HAZARD (S) The HACCP plan does not list the food safety hazard (s) identified in the hazard analysis § 417.2 (c)(1)). (Exception: A HACCP plan for thermally processed/commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X, need not address food safety hazards associated with microbiological contamination (§ 417.2 (b)(3)).	
	HAZARD CONTROL The HACCP plan does not list CCP's for each safety hazard (§ 417.2(c)(2)).	
	The HACCP plan does not list critical limits to be met at each CCP (§ 417.2(c)(3)).	
	MONITORING The HACCP plan does not list the procedures to be used to monitor each CCP and the frequency with which these procedures will be (§ 417.2(c)(4)).	
	CORRECTIVE ACTIONS The HACCP plan does not identify the corrective action to be followed in response to a deviation from a critical limit at a CCP (§ 417.2 (c)(5)).	
	VERIFICATION PROCEDURES The HACCP plan does not list the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed (§ 417.2(c)(7)).	
3. RECORDKEEPING	The HACCP plan's recordkeeping system does not document the monitoring of CCP's and/or does not include records with the actual values and observations (§ 417.2 (c)(6)).	
	ACCEPTANCE AND REASSESSMENT (§ 417.2(d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or (2) at least annually thereafter upon required plan reassessment.	
	MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (§ (d) (2) (ii)).	

FSIS DIRECTIVE 5000.1
Attachment 3

U.S. DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
SANITATION SOP'S -- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	IMPLEMENTATION DATE

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Three, Paragraph II.B.

	REQUIREMENTS	YES (✓)
1. SANITATION SOP'S	The establishment does not have written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s) (§416.12(a)).	
	The Sanitation SOP's do not identify which of the procedures are pre-operational procedures (§416.12(c)).	
	The pre-operational procedures do not address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils (§416.12 (c)).	
	The Sanitation SOP's do not specify the frequency with which the establishment will conduct each procedure (§416.12 (d)).	
	The Sanitation SOP's do not identify the establishment employee or employees responsible for implementing and maintaining specified procedures (§416.12 (d)).	
2. RECORDKEEPING	The establishment does not have identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOP's and any corrective actions taken (§416.16(a)).	
3. DATED SIGNATURE	The individual with overall authority on-site or a higher level official of the establishment did not sign and date the Sanitation SOP's (1) upon initial implementation, or	
	(2) upon a modification (§416.12 (d)).	

FSIS FORM 5000-2 (9/97)

FSIS Directive 5000.1
Attachment 4

U.S. DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
E. COLI-- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Four, Paragraph II.B.

	REQUIREMENT	(YES) (✓)
1. SAMPLING PROCEDURES	The establishment does not have written procedures for collecting samples for E. coli testing.	
	The establishment's procedures do not identify the establishment employee (s) designated to collect sample for E. coli testing.	
	The establishment's procedures do not address	
	(1) the location (s) of sampling,	
	(2) how sampling randomness is achieved, or	
	3) handling of samples to ensure sample integrity.	
	(Paragraph (a) (2) (i) of § 310.25 or § 381.94).	
2. SAMPLE COLLECTION	The establishment is not collecting samples for E. coli testing (Paragraph (a) (1) § 310.25 or § 381.94).	
3. RECORDKEEPING	The establishment is not recording the analytical results of E. coli tests on a process control chart or table (Paragraphs (a) (1) (iii) and (a) (4) of § 310.25 or § 381.94).	

FSIS FORM 5000-3 (9/97)

U.S. DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
***E. COLI* TESTING CHECKLIST - REGULATORY REQUIREMENTS**
(§310.25 OR §381.94) OTHER COMPLIANCE/NO COMPLIANCE

ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS

REQUIREMENTS	YES (✓)
1. SAMPLE COLLECTION	
a. Livestock or poultry sampled (paragraph (a)(1)) The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number	
b. Location and technique3 (paragraph (a) (2)(ii)) The establishment is not collecting samples at the required location in the process.	
(1) The establishment is not collecting samples by: *(as applicable)* Sponging or excising tissue from the required sites on a livestock carcass, or whole-bird rinsing a chicken or turkey carcass, or sponging a turkey carcass	
c. Frequency (*paragraph* (a) (1)(l) and *paragraph* (a) (2)(iii), (a)92)(iv), or (a)92)(v)). (1) The establishment is not collecting samples at the frequency specified in paragraph (a) (2) (iii); or	
(2) In an establishment operating under a validated HACCP plan that has substituted and alternative for the specified frequency pursuant to paragraph (a) (2) (iv): (a) The alternative frequency is not an integral part of the establishment's HACCP plan verification procedures.	
(b) FSIS has determined *(and so notified the establishment in writing)* that the alternative frequency is inadequate to verify the effectiveness of its processing controls.	
d. random selection of carcasses (paragraph (a)(1)(l), (a)(2)(l), and/or (a)(2)(ii))	
(1) In selecting carcasses, the establishment is not following ts written procedures on random sampling.	
(2) The establishment is not collecting samples randomly.	

Requirement	YES (✓)
2. SAMPLE ANALYSIS *(paragraph (a)(1)(ii) and (a)(3))* **a. The laboratory analyzing the samples is not using an AOAC Official Method or another method that meets the criteria in paragraph (a) (3).**	
3. RECORDS OF THEST RESULTS (paragraphs (a)(1)(iii) and (a) (4)) **a. The establishment's process control chart or table does not show at least the most recent 13 *E. coli* test results**	
b. The establishment's process control chart or table does not express *E.coli* test results in terms of: (*as applicable*) cfu/cm^2 of surface area sponged or excised by type of livestock slaughtered, or cfu/ml of rinse fluid by type of poultry slaughtered.	
c. The establishment is not retaining records of test results for 12 months.	
4. Table 1 does not include applicable m/M criteria, and the establishment is not using a statistical process control technique *(charting or plotting the results over time)* to determine what variation in test results is within normal limits.	
5. Table 1 includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria. (An establishment is not determining whether it is operating within these criteria. *(An establishment is not operating within these criteria when the most recent test result exceeds M or when the number of samples out of the most recent 13 samples testing positive at levels above m is more than 3.)*	

FSIS DIRECTIVE 5000.1 Attachment 5

SLAUGHTER PROCESS VERIFICATION METHODOLOGY

Hands-on verification of the pre-operational procedures component of a slaughter establishment's Sanitation SOP's will include utilization of a Pre-Operational Sanitation Inspection Plan. The development of a plan is necessary to provide uniformity in conducting pre-operational sanitation inspection by identifying areas and units for random sampling. Plans will differ with the size of the establishment: Establishments that have 15 or more units will be subdivided into areas and have a certain time allotment as compared to establishments that have 14 or less units, which will not be divided into areas and thus will have a shorter time allotment.

Pre-Op Sanitation Inspection Plans for Slaughter Establishments Having 15 Units or More

A Pre-Op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignments, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-up start time for each assignment:

a. The pre-op start time will be determined by an Inspection program employee based on the Inspection Units (IU's) selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

b. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate areas and identify units in each area:

a. An area is a major portion of an establishment designated in the Pre-Op Sanitation Inspection Plan for hands-on pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. The Inspection program employee will determine the boundaries of each area. One to five areas will be covered during a pre-op inspection assignment.

b. Each area is divided into units. The size of an area may vary from 15 to 50 units. A unit is a numbered three-dimensional section within an area. Each unit must be sufficiently identified so that inspectors who rotate into a pre-op sanitation inspection assignment can easily identify each unit. A unit may have irregular boundaries that are usually identified by landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. A

hand-drawn schematic of the area will be used to identify units. The schematic will include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The boundaries of the units will be drawn on the schematic and the units numbered. To the extent practical, units should be numbered in the order of product flow for each area. Large, complex equipment may be divided into smaller units. For example, a designated unit might be an individual piece of equipment, such as a picker, and the floor, gutter drain, posts walls, and overhead structures in the vicinity of that piece of equipment. The picker may also be divided down the middle and each half included in a different unit. Other examples of units include portions of the area with identifiable boundaries, such as the hide puller, including the floors, drains, walls, and overhead structures and a traffic lane through which products and personnel move.

c. Portable equipment and other equipment that is displaced during cleaning may not always be located entirely within a unit at the time of inspection. Such equipment will be inspected when it is within the boundaries of a unit.

d. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

e. Inspection Units (IU's) will be randomly selected from units in an area:

(1) Upon receipt of the Procedure Schedule (i.e., the week before), an Inspection program employee should select the random IU's for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled. This will allow determination of the lockout/tagout verification time based on the IU's selected. The selected IU's should remain under security. The amount of time for lockout/tagout verification should be communicated to the inspector(s) responsible for performing pre-operational sanitation.

The number of IU's to be selected for area sampling is according to the following schedule:

Units Per Area	Number of IU's
15 to 30	3
31 to 40	4
41 to 50	5

(2) The CS will authorize a method of randomly selecting IU's for inspection. The following method may be used:

(a) Number cardboard chips to correspond with the inspection unit numbers and place them in a container large enough to permit thorough mixing of the chips.

(b) Before each inspection, mix and then select the specified number of chips from the container.

(c) Write the IU numbers that have been selected for inspection on a piece of paper.

(d) Return the chips to the containers.

Pre-Op Sanitation Inspection Plans for Slaughter Establishments Having 14 Units or Less (small establishments)

Pre-op sanitation inspection in small establishments will differ from pre-op sanitation inspection in larger facilities. The Pre-Op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignment, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time:

a. An Inspection program employee will create a Pre-Op Sanitation Inspection Plan. The plan will be filed in the inspector's office or in a file designated for the inspector's use in those establishments that are not required to maintain an inspection office.

b. The pre-op start time will be determined by an Inspection program employee based on the IU's selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

c. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate units:

a. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and must be divided into 1 minute units. Physical boundaries must be specified for each unit in the Pre-Op Sanitation Inspection Plan.

b. Small establishments will not be subdivided into areas.

c. An inspection program employee will select 3 IU's at random for pre-op sanitation inspection as scheduled by the PBIS.

d. An inspection program employee should select the random IU's upon receipt of the Procedure Schedule (i.e., the week before) for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but must be completed at least the day before hands-on verification is scheduled.

SUPPLEMENTARY INSTRUCTIONS REGARDING ENFORCEMENT ACTIONS

When noncompliance with regulatory requirement(s) is found, FSIS inspection program personnel will take action as outlined in FSIS Directive 5400.5 and FSIS Directive 5000.1, Part Three, and consistent with applicable regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

Note: Hands-on verification includes a records review component. Prior to performing the hands-on verification, the inspector will review the establishment's records for that day, if available at that time. The inspector will document findings on FSIS Form 5400-4, Noncompliance Record (NR). When determining if noncompliance exists, you must take into account what is known for a fact. Therefore, if an establishment's records for that day are available, there may be something in the records that would make a difference in determining whether the establishment has failed to comply with one or more regulatory requirements. If the establishment's records for that day are not available, findings written on the establishment's records later will not be known as a fact when a determination is made by the inspector during the hands-on verification.

The regulations on Sanitation SOP's require the establishment to implement procedures sufficient to prevent direct contamination or adulteration of product(s), and pre-operational procedures in the Sanitation SOP's must address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. Therefore, contaminated product and violative facilities, equipment, and utensils, in addition to requiring official control actions, will be considered Sanitation SOP failures. Official control action consists of retention of products and rejecting equipment, utensils, and rooms and/or areas to prevent their use in the production of products until a failure is remedied.

FSIS inspection program personnel will determine whether official control action is appropriate. When the Agency seeks to take further regulatory or administrative action, it must be able to rely on NR information. Therefore, documenting failure to comply with regulatory requirements as specified above is essential (whether or not official control action was taken).

FSIS Directive 5000.1
Appendix B

COMPLETING FSIS FORM 5400-4 WHEN MORE THAN ONE INSPECTOR PERFORMS SANITATION ISP PROCEDURES IN LARGE ESTABLISHMENTS

When multiple inspectors perform an individual ISP procedure, that is 01B or 01C, each inspector will document individual findings. This can be accomplished by one inspector, as consulted on the local level, documenting on the NR, while the remaining inspection program personnel utilize an NR Continuation Sheet for documentation purposes. ALL noncompliance with regulatory requirements must be documented. The NR Continuation Sheet(s) should have the same number as the NR.

The NR should include a statement to indicate the number of the NR Continuation Sheets that are attached. The NR Continuation Sheets will be attached and all the documentation will be provided to the plant manager. It is essential that the failure to comply with regulatory requirement(s), whether documented on the NR or the NR Continuation Sheet, include all information related to the noncompliance. It is important that both are written in a manner to allow "visualization" of the noncompliance. Both the NR and NR Continuation Sheet need to contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's SSOP procedures not followed. Previous noncompliance for the "same root cause" should be included in the documentation and, as instructed in FSIS Directive 5400.5, noncompliance trend information provided. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included.

Because NR information will form the basis of further Agency actions, it will be essential for each person documenting noncompliance with one or more regulatory requirements to include all of the above information.

For example: There are three inspectors at Est. 38 who perform Pre-op verification.

Two inspectors will document their findings on individual NR Continuation Sheets. One inspector documents failure to comply with regulatory requirement(s) on the NR. The NR and NR Continuation Sheets are put together, and the appropriate noncompliance and trend indicator blocks are marked on the NR and the Procedure Schedule. The NR will include a statement that there are two NR Continuation Sheets attached.

In our example, one of the inspectors documenting on an NR Continuation Sheet is responsible for pre-op verification on the slaughter floor. If this inspector finds repeated noncompliance for the "same root cause" on the slaughter floor, he or she is responsible for including this information on the NR Continuation Sheet (including previous PDR and NR numbers and dates). This inspector should also include failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration, as previously documented, and any notification he or she has previously provided to the establishment pertaining to the repeated failure to comply with regulatory requirement(s).