Pathogen Reduction – Generic *E.coli* Testing

OBJECTIVES

To demonstrate mastery of Pathogen Reduction the trainee will:

1. Explain why *E. coli* testing is used.
2. State who conducts *E. coli* testing.
3. Explain what performance criteria are.
4. Describe when procedure 05A01, the basic regulatory requirements for *E. coli* plans, is conducted.
5. Verify the other regulatory requirements for *E. coli* plans by conducting procedure 05A02.
6. Take appropriate enforcement actions for noncompliance with 05A02.

E. coli

Testing for generic *E. coli* is done in slaughter plants by establishment employees. FSIS verifies that the regulatory requirements for testing are met by the plant.

Fecal contamination is one of the principal sources of pathogenic organisms that contaminate carcasses. The best indicator of fecal contamination is *Escherichia coli*, Biotype I, also called generic *E. coli,* because it is commonly found in the intestinal tract of food animals. The intestinal tract is also the primary pathway for contamination of meat and poultry with other pathogens such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. Ongoing *E. coli* testing by slaughter establishments helps them detect the presence or absence of microbiological organisms in order to determine whether the slaughter process is under control or whether carcasses are being contaminated with feces. In other words, testing is an objective process control indicator for fecal contamination.

Sections 310.25 of the meat regulations and 381.94 of the poultry regulations discuss the testing requirements for generic *E. coli* testing by industry.

Performance Criteria

The *E. coli* performance criteria are not enforceable regulatory standards. Criteria are numbers published in the regulations that represent the highest expected microbial loads on carcasses when the slaughter process is in control. Criteria give slaughter establishments guidance about the effectiveness of their system in preventing fecal contamination. Test results that meet the criteria in the regulations provide evidence that the establishment is maintaining adequate process control for fecal contamination and sanitary dressing.

Performance criteria have been developed for some species–not all of them, and for only certain sampling techniques–not all of them. Establishments must use statistical process control to evaluate their test results when they slaughter species or use sampling techniques for which the Agency has not developed performance criteria.

Program Employee Responsibilities

Determining whether an establishment meets the *E. coli* requirements is divided into two procedures: “basic” compliance (procedure 05A01) and “other” compliance (procedure 05A02). Basic compliance addresses regulatory requirements the establishment must meet, whereas other compliance is the actual execution of the requirements.

05A01 - Basic Compliance

In March 1997, an FSIS *E. coli* Special Team visited all slaughter plants across the nation to verify compliance with the basic regulatory requirements for *E. coli* testing. They performed the basic compliance procedure. Since the 05A01 basic procedure is only done once in each establishment, it is only performed now for new plants beginning slaughter operations. Frontline supervisors assess

whether new operations meet the regulatory requirements before a grant of inspection is approved.

The frontline supervisor performs procedure 05A01 using the *E. coli* Testing Basic Compliance Checklist. If the new establishment is not in compliance with the regulations, a grant is not given to the establishment until the requirements are met.

In the event a CSI discovers that the plant does not have a written *E. coli* Testing Procedure, the District Office should be contacted through the proper supervisory channels. The District Office will then provide instructions regarding enforcement activities.

05A02 - Other Requirements

When scheduled by PBIS, in-plant personnel perform procedure 05A02 by completing the *E. coli* Testing Checklist for Other Compliance (FSIS Form 5000-4) in plants that slaughter poultry or livestock covered by the generic *E. coli* testing regulations. The checklist is not in Form Flow. A copy of Form 5000-4 should be printed from Outlook. The form can be found using the following pathway.

Click on Inbox (on the toolbar on top of the messages-not on the side panel)
Double click on Public Folders
Double click on All Public Folders
Double click on Agency Issuances
Double click on Forms
Click on FSIS 5000 Series
Click on 5000-4

The *E. coli* Testing Checklist for Other Compliance considers execution of the specific regulatory requirements. Other *E. coli* testing requirements are met if the plant successfully executes the activities addressed in its written procedure, analyzes samples, and keeps records of test results. In-plant program employees should read and answer each statement on the checklist. If the answer to all of the statements is "no," the plant is in compliance, and only the establishment information and date are completed at the top of the checklist page when noncompliance is not found. The checklist is kept in a government file.

If the answer is "yes" to any of the statements, there is noncompliance. An *E. coli* Testing Cheat Chart (Attachment 2 of this module) is provided as a reference about species tested, testing frequencies, sample locations, sample sites, and sampling methods allowed by regulation. It makes a quick and easy procedure aid when conducting 05A02.

A copy of the Other Checklist, which was developed from regulations 310.25 and 381.94, follows.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE ***E. COLI* CHECKLIST—REGULATORY REQUIREMENTS** **(§ 310.25 OR § 381.94) OTHER COMPLIANCE/NONCOMPLIANCE**		
ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS
REQUIREMENT		YES (√)
1. SAMPLE COLLECTION **a. Livestock or poultry samples (*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 technique *(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 poultry carcass, or sponging a turkey carcass.		
c. Frequency *(paragraph (a) (1) (i) and paragraph (a) (2) (iv), or (a) (2) (v))* The establishment is not collecting samples at the frequency specified in paragraph (a) (2) (iii); or		
In an establishment operating under a validated HACCP plan that has substituted an 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) (i), (a) (2) (i), and/or (a) (2) (ii)* (1) In selecting carcasses, the establishment is not following its 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 TEST RESULTS *(paragraph (a) (1) (iii) and (a) (4)* a. The establishment's process control chart or tables 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 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)*	
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 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).*	

Consumer safety inspectors must understand what each statement means in order to conduct procedure 05A02. The following addresses each statement on the checklist individually.

1. SAMPLE COLLECTION

a. Livestock or poultry samples (*paragraph (a) (1)*)

The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.

E. coli testing must be done in establishments that slaughter any market class of cattle, swine, sheep, goats, horses, mules, equines, chickens, ducks, geese, guineas, turkeys, squab, and ratites.

If a combination of types of livestock or poultry is slaughtered, the establishment samples only from the species it slaughters in the largest number. It is only necessary to sample one type of livestock or poultry to determine whether sanitary dressing controls are effective. *E. coli* tests measure the effectiveness of the process regardless of which species is slaughtered. This means, for example, if an establishment slaughters both chickens and ducks, but mostly chickens, they should be testing chickens for generic *E. coli*.

1. b. Location and technique *(paragraph (a) (2) (ii)*

The establishment is not collecting samples at the required location in the process.

In-plant program personnel should remember the following things when considering the statement above.

- The location refers to the place within the establishment where the sample is collected.
- Livestock samples are collected after they have been in the cooler for a minimum of 12 hours. There is no maximum time limit. Carcasses can be selected while on the rail or after the final wash and set aside in a convenient spot in the cooler for testing after cooling. In cases where the carcasses are inaccessible in the cooler, or employee safety is jeopardized, it is acceptable to select random samples before carcasses enter the cooler.
- Poultry samples are collected at the end of the chiller or drip line or at the last readily accessible point prior to packing or cut-up.
- Hot-boning operation samples are taken after the final wash prior to boning.

1. b. (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.

The sampling site refers to places on the carcass where samples are collected.

There are three sampling methods an establishment may use to collect *E. coli* samples.

- Excision sampling
- Sponging
- Whole-bird rinsing

Excision sampling is aseptically cutting a surface section from the carcass and sending the tissue sample for laboratory analysis. Excising tissue from a carcass is, of course, a destructive method of sampling.

Sponging is aseptically swabbing the surface of the carcass with a sterile sponge and sending the sponge to the laboratory for analysis. Sponging is a nondestructive method of sampling.

Whole-bird rinsing is shaking the whole carcass, or all the component parts that constitute a whole carcass (Notice 56-02), in a bag with a sterile sampling solution, collecting the rinse fluid, and sending the fluid to the laboratory for analysis. This is also a nondestructive technique.

The chart below provides an easy reference for species and the sampling methods allowed.

Excision	Sponge	Whole-bird Rinse
Beef	Beef	Chickens
Swine	Equine	Ducks
	Geese	Geese
	Goats	Guineas
	Sheep	Turkeys
	Swine	Squabs
	Turkeys	
	Ratites	

Notice that beef and swine may be sampled by excision or sponging and that turkeys and geese may be sampled by either the sponging or the whole-bird rinse method.

Samples must be taken from specific sites on livestock carcasses. The three sites from which excision samples on cattle or sponge samples on cattle, sheep, goat, and equine carcasses must be taken are the:

- Flank
- Brisket
- Rump

In the case of hide-on carcasses for the above species, the samples must be taken from:

- Inside the flank
- Inside the brisket
- Inside the rump

For swine carcasses, three excision or sponge samples must be taken from the:

- Belly
- Ham
- Jowls

For poultry, the whole bird is rinsed in a sterile solution and the rinse is sampled. In the case of poultry that may be sponge-tested, samples must be taken from the:

- Back
- Thigh

1. c. Frequency *(paragraph (a) (1) (i) and paragraph (a) (2) (iv), or (a) (2) (v))*

(1) The establishment is not collecting samples at the frequency specified in paragraph (a) (2) (iii); or

For *E. coli* testing purposes, slaughter establishments are divided into two categories: very low volume plants (VLV) and greater than very low volume plants (>VLV). The categories of plants are based on the plant's annual slaughter volume.

Very low volume plants are described as follows:

- Cattle, goats, sheep, horses, or other equine: Annually slaughter fewer than 6,000 head
- Swine: Annually slaughter fewer than 20,000 swine
- Livestock combination: Annually slaughter fewer than a combination of 6,000 cattle, plus sheep, goats, horses, or equines that equal no more than 20,000 animals total
- Chickens, ducks, guineas, or geese: Annually slaughter fewer than 440,000 birds.
- Turkeys: Annually slaughter fewer than 60,000 turkeys
- Squab: Annually slaughter fewer than 6,000
- Ratites: Annually slaughter fewer than 60,000
- Chicken, ducks, guineas, geese, or turkey combination: Annually slaughter fewer than 60,000 turkeys and fewer than 440,000 birds total

Very low volume establishments begin sampling the first full week they operate after June 1st. They continue collecting at least one sample per week in each week they operate until 13 samples are completed. The series of 13 tests must show process control before the series can be ended. If the 13th test indicates that the sanitary dressing process is out of control the establishment must continue to test until process control is regained.

The 13 samples should not be collected in one day or even one week. Sampling over a period of time provides a better indication of the process control of the establishment than taking all samples at once.

Seasonal VLV operations must complete all *E. coli* testing during whichever months it operates. For example, a seasonal duck slaughter plant that operates from September through December must begin testing during its first full week of operations and complete 13 tests before operations end in December.

When a VLV establishment that has completed 13 tests for the year makes changes like remodeling, new equipment, new employees, or new procedures that affect how well the process works, weekly testing must be resumed until another series of 13 tests can establish the effectiveness of the changed process. If FSIS determines there have been changes that affect the process, the information must be provided to the company in writing. The establishment would then be required to resume *E. coli* testing to judge the process control.

Establishments slaughtering more than the numbers indicated above for VLV plants are classified as greater than very low volume plants.

Greater than very low volume establishments use the following frequencies for testing.

Cattle, sheep, goats, horses, or equines	1 test per 300 carcasses
Swine	1 test per 1,000 carcasses
Chickens	1 test per 22,000 carcasses
Turkeys, ducks, guineas, geese, squab, and ratites	1 test per 3,000 carcasses

Greater than very low volume establishments must sample at the above frequencies or a minimum of at least once per week, whichever is greater. For example, an establishment that slaughters 9,000 cattle per year must sample once per week (a total of 52 samples per year), not only 30 samples per year as indicated by the 1 test per 300 carcasses frequency (30 samples for 300 carcasses = 9,000 carcasses).

Slaughter volume does not always match frequency rates in the regulations. Establishments should account for extra slaughter volume. This can be done by conducting additional tests. For example, a chicken plant that slaughters 40,000 birds per day should test at least once a day at the 22,000 birds per test frequency. However, the remaining 18,000 birds should also be accounted for to monitor process control. To account for the extra slaughter volume, the establishment could “carry over” the 18,000 extra birds to the next day’s volume and conduct two (2) *E. coli* tests on the second day.

1. c. (2) In an establishment operating under a validated HACCP plan that has substituted an 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.

Establishments may substitute an alternative testing frequency for the one in the regulations by including *E. coli* testing in their HACCP plan. The alternative frequency must be part of the establishment's verification procedures for its HACCP plan. For example, the establishment might have a CCP where generic *E. coli* testing is written into their HACCP plan to monitor the CCP. The critical limit for test results must be equal to the regulatory performance criteria (when available) or the plant's statistical process control limit for *E. coli* colonies. The plant may then change the frequency to the one written into the HACCP plan. It may not change the regulatory performance criteria or the limits determined by statistical process control.

1. c. (2) (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.

An FSIS employee, like an inspector in charge (IIC), consumer safety officer (CSO), or frontline supervisor, who analyzes the *E. coli* testing program and the HACCP plan into which it is incorporated, might decide that the testing frequency does not adequately determine whether the slaughter process is effectively controlling microbial contamination. In that case, a written notice must be given to the establishment. Check yes in the block if there is such a letter on file.

1. d. Random selection of carcasses *(paragraph (a) (1) (i), (a) (2) (i), and/or (a) (2) (ii)*

(1) In selecting carcasses, the establishment is not following its written procedures on random sampling.

Regulations require that carcasses for sampling be selected at random. Different methods, like random number tables, computer-generated random numbers, or drawing cards, may be used. Whatever the establishment chooses to use must be written into the *E. coli* procedure.

1. d. (2) The establishment is not collecting samples randomly.

The random method selected by the establishment and written into its plan must be followed. The program employee must be familiar with the written random sampling plan.

In cattle, each half-carcass represents one unit eligible for sampling. Both the "leading" and "trailing" sides of a carcass should have an equal chance of being selected within the

designated time frame. In other livestock species, each whole carcass represents one unit eligible for sampling.

If more than one shift is operating at the plant, the sample can be taken from either shift, provided the sample selection time is based on the appropriate sampling frequency.

The half-carcass or carcass for sampling must be selected at random from all those eligible, so if there are multiple lines or chillers, randomly select the line or chiller from which the sample will come during each collection interval.

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).

Some establishments conduct their own analyses. FSIS assumes that meat plants following the "Guidelines for *E. coli* Testing for Process Control Verification in Cattle and Swine Slaughter Establishments" and poultry plants following the “Guidelines for *E. coli* Testing for Process Control Verification in Poultry Slaughter Establishments" will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results. Because these guidelines are not regulatory requirements, the plant may choose to use a comparable sampling technique and be in compliance.

Plant lab employees might have a book of AOAC procedures or articles from peer-reviewed scientific journals that describe their procedure.

When in doubt about whether a testing procedure is acceptable, program employees should go through the supervisory chain-of-command to the District Inspection Coordinator for assistance.

Sample techniques used by plant employees can be found in Attachment 1 at the end of this module.

3. RECORDS OF TEST RESULTS *(paragraph (a) (1) (iii) and (a) (4)*

a. The establishment’s process control chart or tables does not show at least the most recent 13 *E. coli* test results.

Establishments must keep records of *E. coli* test results for one year. They are also required to keep a table or a chart of the results for at least the most recent 13 test results. Establishments are not required to maintain a file of actual laboratory reports received from either an in-house laboratory or an outside laboratory.

In-plant program personnel should consider the length of operations. In cases where the establishment has not been operating long enough to have 13 test results, there is not noncompliance for a lack of testing.

3. b. The establishment's process control chart or table does not express *E. coli* test results in terms of: *(as applicable)*

CFU/cm^2
CFU/ml of rinse fluid by type of poultry slaughtered

E. coli tests are reported in quantity (number of colonies on an agar plate). Each test result must be recorded in terms of colony forming units per square centimeter (cfu/cm^2) for excision and sponge test results and in colony forming units per milliliter (cfu/ml) for whole-bird rinses. In-plant program personnel should match the units of measure with the testing technique used to ensure that results are reported correctly.

3. c. The establishment is not retaining records of test results for 12 months.

Establishments must keep records of the tables and charts with *E. coli* test results for 12 months. Establishments are not required to maintain a file of laboratory reports received from either an in-house laboratory or an outside laboratory.

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)*

In-plant program personnel should refer to the *E. coli* regulations. If the Agency does not have performance criteria published for the species being sampled or for the sampling technique being used, the establishment should use statistical process control values to document *E. coli* test results.

Livestock baseline studies conducted to arrive at the performance criteria printed in the regulations were performed on cattle and swine only, using excision testing. Therefore, when the sponge method is selected for sampling any species, the performance criteria do not apply. The establishment must use statistical process control for evaluating test results. For example, if a livestock establishment uses sponge sampling, statistical process control must be used- not the m/M criteria.

Except those slaughtering chickens, all poultry establishments must use statistical process control. m/M criteria are only available for chickens using the whole-bird rinse.

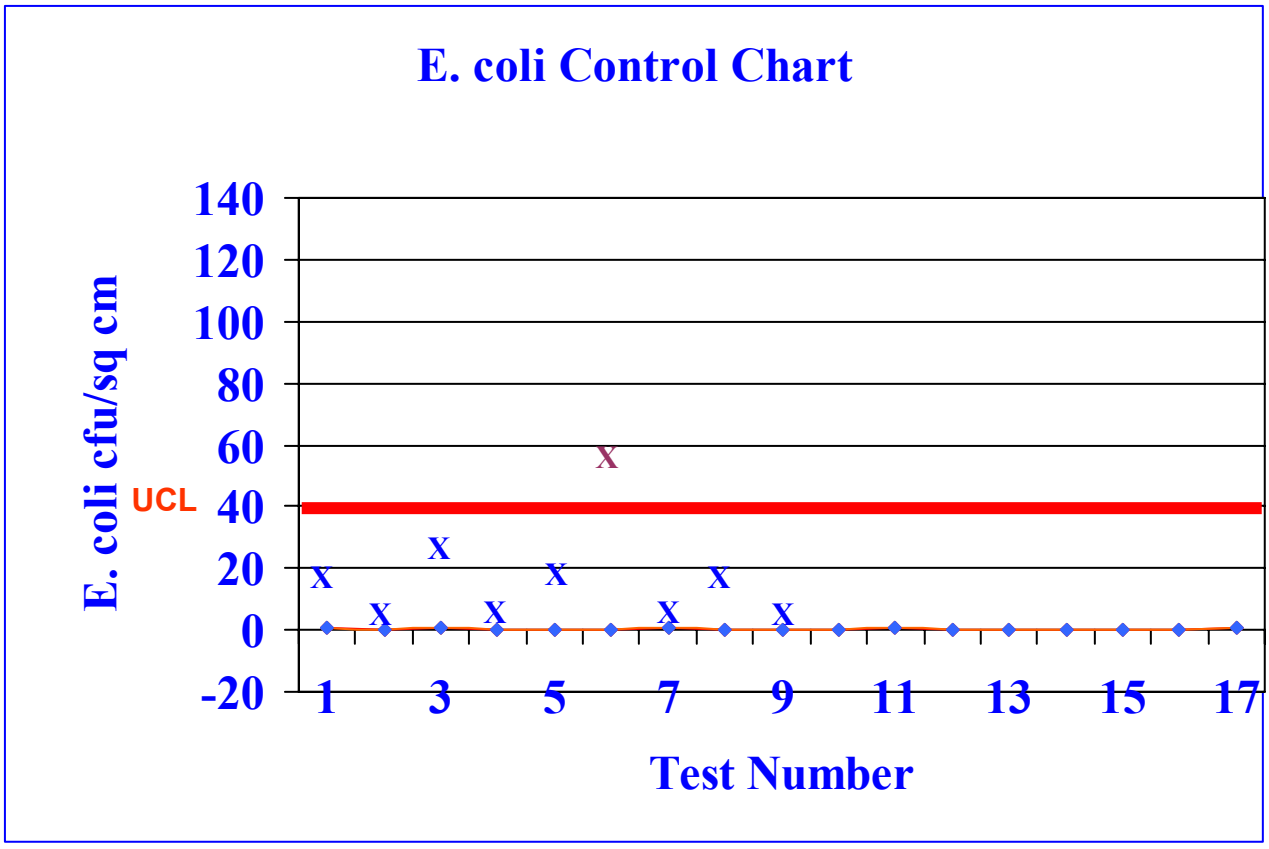
Statistical process control, used when the regulations do not cite performance criteria, begins when the plant conducts a series of preliminary generic *E. coli* tests during its own slaughter operations. They chart the results in cfu/cm^2 or cfu/ml to determine the typical range of generic *E. coli* counts found at their establishment under normal circumstances. After a company collects test results long enough to believe it has a true picture of its performance, it sets its own upper and lower control limit based on test results. There are no regulatory requirements for how statistical process controls are determined. Companies may use a variety of valid methods to determine limits for statistical process control. For example, establishments may calculate their own statistics, hire a consultant company, or use a software package to develop statistical process control values. Once the values are

determined, and as long as the data points on the company chart stay within the control limits set by the company, the process is considered in control.

An example of a method a company may use to develop a statistical process control program is as follows. The establishment:

- Conducts a series of preliminary generic *E. coli* tests during operations.
- Charts the results in cfu/cm2.
- Determines the typical range of generic *E. coli* counts found normally.
- Collects test results long enough to have a true picture of its performance (about 30 days usually)
- Sets upper and lower control limits based on test results.

The following example of a statistical process control chart plots test results in terms of time along the horizontal X-axis against test results along the Y-axis. This establishment set a centerline value for its process control, which indicates the center point of the acceptable range of test results. The upper control limit line marks the highest test result value considered acceptable by the company. The test result shown at test number 6 is above the upper control limit. The company recognized that this result was probably due to a variation in its process that needed to be identified, eliminated, and prevented from recurring. According to the chart, the plant correction was effective because the following test result was back in the acceptable range.



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 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).*

In-plant program personnel should refer to the *E. coli* regulations. If the Agency does have performance criteria published for the species being slaughtered and the sampling technique, the establishment should use m/M values from the regulations to document *E. coli* test results.

Cattle and swine establishments that choose excision of three sites must use the m/M performance criteria published in the regulations for evaluating test results when they are available. Regulatory m/M criteria apply only to swine and cattle sampling when the excision sampling technique is used and to chickens when the whole-bird rinse technique is used.

When performance criteria are printed in the regulations, the *E. coli* test results are compared to the regulatory criteria and fall into one of three categories: acceptable, marginal (represented by "m"), and unacceptable (represented by "M").

- Marginal results ("m") are those that fall within the worst 20% of overall industry performance in terms of *E. coli* counts (results taken from baseline study). More than three marginal results in the last 13 tests are unacceptable.
- Results in the worst 2% of overall industry performance (results taken from the baseline study) are called the maximum or "M" value. Any single test result exceeding "M" is unacceptable.

The m/M values taken from the regulations are applied to a moving window of the last 13 documented test results. That means that the establishment considers all of the last 13 test results when determining if the process is in control. Every time a new test result is added to their records, the oldest test is dropped and the new test becomes one of the most recent 13 results.

For the sanitary dressing process to be judged in control no more than 3 sample results can be above the "m" marginal line. If 4 are above "m", the process is out of control.

If the test result of the most recent sample and is above "M" maximum, the process is automatically out of control, regardless of the previous test results. Once another test result is entered in the chart or table, the "M" test simply becomes another result considered to be above the "m" line. It no longer carries the consequence of causing "automatic" process control failure.

After the sanitary dressing procedure is judged to be out of control, a subsequent test result below the "m" line indicates that the establishment did something to correct a problem and bring the process back into control. (This correction does

not have to be documented anywhere.) However, the process is not judged totally in control until the window of 13 tests also shows process control.

The following table from the regulations shows the m/M values for *E. coli* performance criteria set by the Agency.

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

The above table establishes performance criteria only for excision testing of cattle and swine and whole-bird rinsing of chickens.

An example of how to use the table is to consider a cattle slaughter establishment. An *E. coli* test result is:

- Acceptable if it comes back negative
- Marginal if the test result is positive but not above 100 cfu/cm^2
- Unacceptable if it is above 100 cfu/cm^2

The following table is an example of one that may be used by plants for record keeping.

Test #	Date	Test Result (cfu/cm^2)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail?
1	10-07	10	No	Yes	1	Pass
2	10-07	Negative	No	No	1	Pass
3	10-08	50	No	Yes	2	Pass
4	10-08	Negative	No	No	2	Pass
5	10-09	Negative	No	No	2	Pass
6	10-09	Negative	No	No	2	Pass
7	10-10	80	No	Yes	3	Pass
8	10-10	Negative	No	No	3	Pass
9	10-11	Negative	No	No	3	Pass
10	10-11	Negative	No	No	3	Pass
11	10-14	50	No	Yes	4	Fail
12	10-14	Negative	No	No	4	Fail
13	10-15	Negative	No	No	4	Fail
14	10-15	Negative	No	No	3	Pass
15	10-16	Negative	No	No	3	Pass
16	10-16	Negative	No	No	2	Pass
17	10-17	120	Yes	No	3	Fail

Looking at this plant record the following determinations can be made.

1. Test number eleven, conducted on October 14, documents the fourth test result in the marginal (“m”) range. Therefore, the plant was in an unacceptable process control status because the fourth marginal result exceeds the limit of no more than three marginal results in the past 13 consecutive tests.

Program employees should focus on dressing procedures and sanitation performance standard requirements when failing test results indicating lack of process control are observed.

2. Tests number twelve and thirteen are negative, and therefore in the acceptable range. However, considering the last 13 test results in the 13-test moving window, there are still more than three results in the marginal range. The company marked its record to show that it is still failing because there are four marginal test results. In reality this is not an unacceptable result because tests twelve and thirteen are negative, indicating the process is back in control, but there is evidence of problems in the recent past.

3. For test number fifteen the number of marginal results in the last thirteen tests window is reduced to three. The marginal result for test number one is dropped and replaced by an acceptable result as the 13-test window moves ahead one test.

4. The test result for test number seventeen exceeds 100 cfu/cm^2, the "M" value for cattle. Any result over 100 cfu/cm^2 is automatically unacceptable. It takes only one test in the "M" range to indicate the establishment may not have adequate process control.

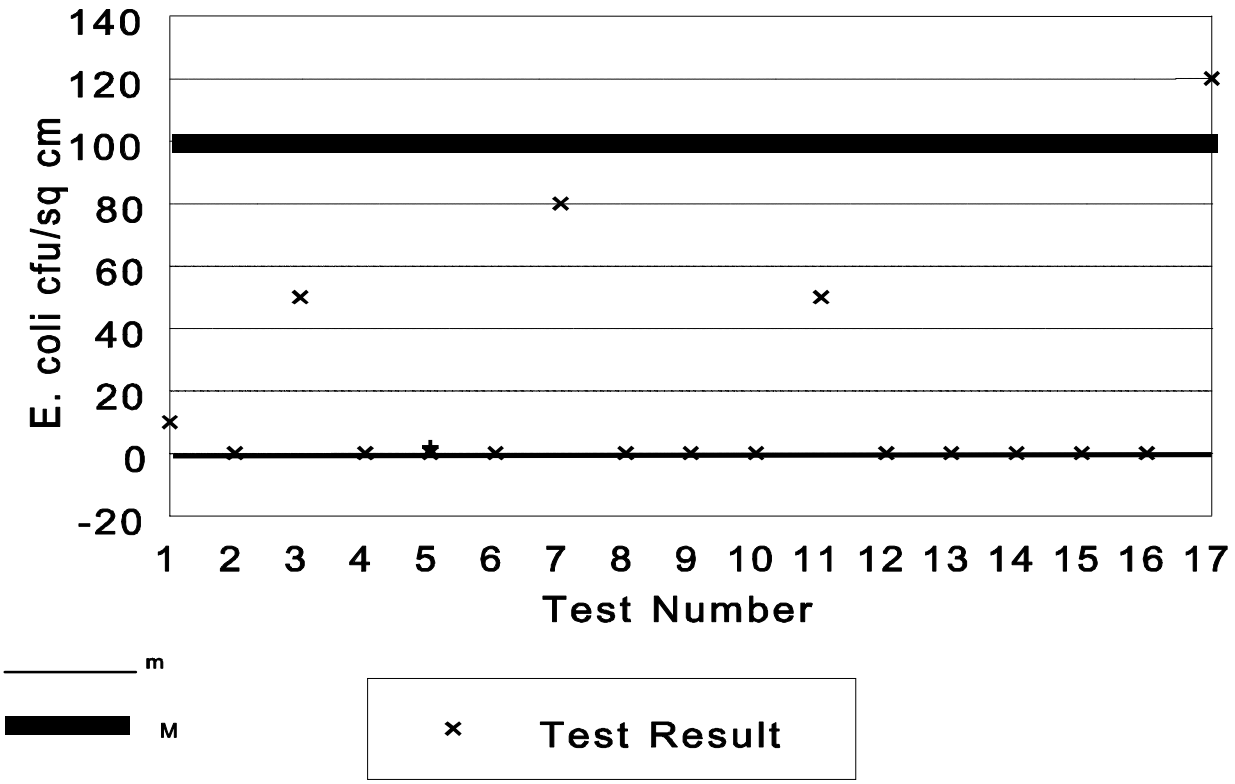
   Inspection personnel reviewing this record should focus on sanitation performance standard requirements.

Another method the company may use to document its *E. coli* test results is a control chart. The seventeen test results written in the previous table are plotted on the following control chart.

The vertical Y-axis shows how many colony forming units (cfu) of *E. coli* were found in a square centimeter (cm^2) of media at the laboratory. The horizontal X-axis indicates the test number. Marking an "X" at the point the X and Y-axes cross shows each test value. For ease of reading, the chart has a line to indicate the bottom limit of "m", and a thicker line to indicate the upper limit of "m." Any "X" plotted between the thin line and the thick line falls in the marginal range we call "m." Any "X" plotted above the thicker line is in the unacceptable range, or "M."

E. Coli Control Chart

Figure 4



Whenever a prudent plant determines that its *E. coli* test results do not meet m/M performance criteria or statistical process control values, it should take corrective action to bring the process back into control. Under the regulations, plants are not required to take corrective actions or to document corrective actions for *E. coli* test failures. However, when establishments do not evaluate their test results (§318.94(a)(5) or §325.10), they might not be maintaining process controls sufficient to prevent fecal contamination.

Sample Integrity

Sample integrity is not addressed on any of the checklists to determine compliance, but it cannot be ignored. It must be addressed in the plant's written specimen collection procedure and should be followed; but if it is not followed, it is not an enforceable issue. If inspection personnel observe circumstances that seem to jeopardize sample integrity (e.g., freezing the sample, not shipping the sample on the same day it is collected), the District Office should be notified through channels. Further investigation of the situation and any enforcement actions will be directed from the District Office.

05A02 - Other Documentation

Whenever FSIS personnel answer “yes” to any item on the *E. coli* Other Checklist, noncompliance exists. It should be documented on a Noncompliance Record. The trend indicator marked on the NR will always be “other” or “n.”

A copy of the completed checklist should be attached to the file copy of the NR. As soon as possible, or at least by the end of the tour of duty, give a copy of the NR to management. The establishment should respond to the NR either verbally or in writing.

05A02 - Other Enforcement

FSIS *E. coli* criteria are guidelines, not regulatory standards. FSIS does not use company test results to take regulatory action. *E. coli* test results that show lack of process control should be considered in conjunction with other information, like SSOP and HACCP performance.

Further enforcement action might be necessary if the establishment repeatedly fails to implement appropriate immediate action or further planned action in response to NRs documenting noncompliance. In these cases, the inspector in charge (IIC) should notify the District Office through channels. The District Office will give instructions for additional enforcement action when necessary.

Attachment 1

E. coli Sampling Techniques

Step-by-step descriptions of examples of techniques for sponge and whole-bird rinse sampling techniques are included in this section.

Aseptic techniques should be used for all sampling. Extraneous organisms from the environment, hands, clothing, sample containers, sampling devices, etc., may contaminate samples and lead to nonrepresentative analytical results. Aseptic sampling techniques and clean, sanitized equipment and supplies are a must.

An area should be designated for preparing sampling supplies. A stainless steel, wheeled cart or table could be useful during sampling. A small tote or caddy could be moved to the location of sampling and used for carrying supplies. Sample bags could be placed on the tote or caddy when sterile solutions are added to the bags. But these are just ideas and suggestions, not regulatory requirements.

Sterile gloves should be used for collecting samples. Nothing should contact the external surface of the glove except the exposed sample being collected or the sterile sample utensil, such as a specimen sponge. Keep in mind that the outside surfaces of the sample container are not sterile. The following procedure for putting on sterile gloves can be followed when collecting samples.

The package of sterile gloves is peeled open from the top without contaminating the exterior of the gloves by breathing on them, or touching them.

A glove is removed by holding it by the inner surface of the wrist-side opening. Any contact with the outer surface of the glove must be avoided. The washed and sanitized hand is inserted into the glove. Care should be taken not to puncture the glove. The exterior surface of the glove must not be contaminated. This step is repeated for the other hand.

If at any time there is concern that a glove might be contaminated, this entire process must be repeated with a sterile pair of gloves.

The sponging method of sample collection for swine is described below.

- Sterile sampling supplies include are a pair of gloves, a sponge in a Whirl-pak® bag, a 10 cm x 10 cm sterile template, and 10 milliliters of a sterile sampling solution.

- Prior to actually taking the sample, the plant employee randomly determines where and at what time to take the sample, gathers the sampling supplies, labels the sponge bag, and sanitizes the contact surfaces.

- At the sample location, the plant employee chooses the sample, allowing sufficient room to safely collect the sample. The carcass belly is sponged first, continuing to the ham and, finally, the jowl area. By wiping with the

sponge in this order of "least to most" contaminated spots, contamination is not spread on the carcass.

- A ladder or similar equipment needs to be positioned near enough to the carcass to easily and safely sponge the ham.

- It is important to avoid touching sterile surfaces. The sponge bag is opened by holding a corner of the wire closure and tearing off the clear perforated strip at the top of the bag. The two white tabs should be pulled to open the mouth of the bag. The inner surface of the bag must not be touched. The employee removes the cap from the sterile sampling solution container and pours all of the solution into the sponge bag. The bag is held closed and the sponge is massaged through the bag. This hastens the sponge's absorption of the solution.

- When the sponge is fully moistened, the employee must carefully push it to the upper part of the bag and open the bag. The wire closure should keep the bag open, as well as keep the sponge in place at the opening. It should be set aside, being careful not to contaminate the sponge.

- Next, the template bag is carefully opened and set aside.

- The employee puts on the sterile gloves, and then carefully removes the sponge without touching the bag. This is done with the hand used to sponge the carcass, which is called the "sampling hand."

- With the other hand, the employee removes the template from its bag. It must be handled only by the outer edges.

- The employee lays the template over the section of the belly to sample. This is close to the underarm section. The sampling area and the inner edge of the template must not be touched. One of two sponging techniques may be used. Either of these may be used, but only one is used per site.

    1) Start at the top of the area in the template. The employee wipes down firmly but not hard enough to crumble the sponge. An even pressure sufficient to remove dried blood is used. The sponge is lifted at the end of one wipe and then rotated. If the sponge is not lifted during the rotation, it might contact other surfaces. It is important that the same side of the sponge always contact the carcass. This procedure is repeated for 10 vertical wipes. Then the sampling hand is turned and 10 horizontal wipes are completed. Each pass of the sponge counts as one wipe. It may be necessary for the plant employee to roll the template when sponging since the carcass surface is not flat. Next, the employee transfers the template to the "sampling hand" to safely climb the ladder or platform. The free hand is used to grip hand holds or rails. Once at a convenient and safe height for sampling the ham, the employee must transfer the template back to the other hand and lay it over the ham. The inner edges of the template or

section of the ham site being sampled must not be touched. The same side of the sponge used for the belly is used to sponge the ham.

2) The second sponging technique is accomplished by wiping downward. When the sponge reaches the bottom, it is lifted and started at the top again. This is done 10 times vertically and another 10 times horizontally. The sponge must not contact anything but the area inside the template. The template is transferred back to the sampling hand and the employee climbs down. The sponge is turned over and the unused side of the sponge is used to properly sponge the jowl area. The sponge is then put back into its bag. Excess air is expelled and the top edge of the bag is folded over 3 or 4 times. Then, the wire is folded back against the bag.

The technique for sponge sampling beef half-carcasses is described below.

- The procedures for randomly selecting the location and the sample, and then preparing the supplies, sampling area, and the employee are the same as for swine. The supplies are also the same.

- Sponging samples are taken at the flank, brisket, and rump, in that order, from “least to most” contaminated. A ladder or safe climbing tool will probably be needed to sponge the rump. As directed for swine, the sponge bag is opened; the sponge is moistened with the sterile sampling solution; the template bag is opened; the gloves are donned aseptically; the template is laid over the sample area; and the sampling area is sponged 10 times each vertically and horizontally. The template might need to be rolled. This sponging sequence is repeated for the brisket area, using the same side of the sponge.

- The employee then carefully transfers the template to the “sampling hand” and climbs the ladder. The template is returned to the other hand. The sponge is turned over and the rump area is sampled with the unused side of the sponge.

- The employee climbs down the ladder, again using the handrail. Care must be taken to avoid contaminating the sponge. The sponge is put back in its bag. Excess air is expelled and the bag is sealed.

The technique for sponge sampling turkey carcasses is described below.

- Sponge samples for turkeys and geese are taken similarly to livestock sponge samples. However, the supplies differ. The plant employee uses two pairs of sterile gloves, a sponge in a Whirl-pak® bag, 10 milliliters of a sterile sampling solution, and a 5 cm x 10 cm sterile template. The sterile solution must be clear. It must be refrigerated and chilled before use.

- The supplies, sampling area, and employee are prepared the same as for sampling livestock. To prevent the carcass from slipping while sampling,

clean paper towels, tray-pack absorbent pads, or a sanitized wire rack can be placed under the turkey on the sanitized sampling work surface.

- There are two sample sites on a turkey or goose carcass-the back and the thigh.

- The employee puts on a pair of sterile gloves. A whole, untrimmed turkey carcass, with or without a neck, is randomly selected at the end of the chiller or drip line. The employee must grasp the turkey by its drumsticks without touching the back or thigh area.

- The carcass is taken to the sample area and carefully placed breast down on the towels. The carcass may lean on one side of the breast, but the back and the thigh to be sampled must not touch supporting surfaces.

- The sample-taker removes and discards the gloves that became contaminated while collecting the carcass.

- The sponge bag is opened. The employee pours all of the sterile sampling solution into the sponge bag and completely moistens the sponge. The sponge is pushed to the top of the bag and set aside. The template bag is opened and set aside also. If the template is not in a sterile package, it must be sanitized before use. It must be completely dry before it is used on the turkey.

- The employee then puts on the second pair of sterile gloves and carefully removes the sponge without touching the bag. This is done with the hand that will be used to sponge the carcass (the “sampling hand”).

- With the other hand, the employee removes the template from the bag and handles it only by the outer edges.

- The template is laid over the site on the back to be sampled--a location that is over the vertebral column and just in front of the tail. The template should be equally spaced on either side of the vertebral column. The enclosed sampling area or the inner edge of the template must not be contaminated. Either of the two sponging techniques mentioned earlier with swine may be used to make the 10 horizontal and 10 vertical wipes. The same side of the sponge must always be in contact with the carcass. The template may need to be rolled since the turkey surface is not flat.

- Next, the template is placed over one of the thighs. The sample site starts at the hip joint and extends to cover the thigh. The sampler must turn the sponge over and use the “clean” side of the sponge, holding it by its edges only. The sponge cannot contact anything but the area inside the template.

- After sponging the thigh, the sampler sets the template aside and puts the sponge back into its bag. The air is expelled and the bag is sealed.

The technique for rinsing whole poultry carcasses is described below.

- The whole carcass, or all the component parts that constitute a whole carcass, is rinsed in a bag containing sterile sampling solution. A whole carcass representative of the lot of birds is selected.

- The supplies needed for a whole-bird rinse are a pair of sterile gloves, one large and one small zip-lock bag, 400 milliliters of sampling solution (600 ml for turkeys), and a sealed container. The sampling supply, contact surfaces, and the sample-taker are prepared as mentioned earlier.

- The sample-taker carefully opens the large zip-lock bag without touching the sterile inside surface. The opened bag can be laid on its side on a sanitized surface.

- Sterile gloves are put on, using aseptic technique. The employee should use only one hand to select the carcass. Holding it by the legs, the employee removes it from the line. Excess fluid in the body cavity must be drained.

- With the other hand, the sampler picks up the open sample bag and places the bird in it so that the vent and legs are toward the bag opening. The employee must not touch the inside of the bag.

- The bottom of the open bag may rest on a sterile surface. The employee uncaps the sterile sampling solution and pours all of it into the carcass cavity. Most of the air is expelled from the bag and it is zipped closed. The bottom of the bag is supported with one hand and the top of the bag with the other. The bird in the bag is inverted 30 times. This takes about one minute to ensure that all interior and exterior surfaces are rinsed thoroughly.

- The sampler sets the bag aside and opens the small zip-lock bag. The cap is removed from the sample container and placed in the zip-lock bag to keep it from getting contaminated. Neither the inside of the cap nor its container may be touched.

- The bag containing the bird is opened. With one hand, the sampler holds the carcass through the bag by its leg. With the other hand, the sampler holds the top corner of the bag to form a “V” at the bottom corner. Using this “V” as a pour spout, the sampler carefully pours the rinse fluid into the open sample container. It is only filled to the 30 milliliter volume line. The bag is set aside again. The sampler takes the cap out of the bag and closes the sample container of rinse fluid, securing the cap.

- The sample container is then put into the small zip-lock bag, the excess air is expelled, and the bag is zipped closed. The remainder of the rinse fluid is poured into a drain and the carcass is returned to the point at which it was selected.

Samples must be stored at refrigeration temperatures until the analysis is run. They must not be frozen. The analysis must be run as soon as possible. If the establishment does not have an in-house laboratory, then the sample must be sent to an outside lab for analysis. Some samples may be hand-carried, but others might need to be mailed. The sample has to be as fresh as possible for analysis.

Attachment 2

E. COLI TESTING CHEAT CHART

SPECIES	TEST FREQUENCY	TEST LOCATION	SAMPLE SITES	SAMPLING METHOD
Cattle	1/300 carcasses or 1/wk. – whichever is greater	Carcass cooler >12 hrs. Hot boned: after final wash	Flank, brisket, rump	Excision* Sponging
Chickens	1/22,000 carcasses or 1/wk. – whichever is greater	End of chilling process, after the drip line Hot boned: after final wash	Whole-bird	Whole-bird rinse*
Ducks, Guineas	1/3000 carcasses or 1/wk. – whichever is greater	End of slaughter line Hot boned: after final wash	Whole-bird	Whole-bird rinse
Hide-on carcasses	1/300 carcasses or 1/wk. – whichever is greater	Chilled carcasses	Inside flank, inside brisket, inside rump	Excision for cattle* Sponging
Horses, Mules, Other Equines	1/300 carcasses or 1/wk. – whichever is greater	Chilled carcasses Hot boned: after final wash	Flank, brisket, rump	Sponging
Sheep and Goats	1/300 carcasses or 1/wk. – whichever is greater	Chilled carcasses Hot boned: after final wash	Flank, brisket, rump	Sponging
Swine	1/1000 carcasses or 1/wk. – whichever is greater	Carcass cooler >12 hrs. Hot boned: after final wash	Belly, ham, jowls	Excision* Sponging
Turkeys, Geese	1/3000 carcasses or 1/wk. – whichever is greater	End of chilling process, after the drip line Hot boned: after final wash	Whole-bird OR Sponge back and thigh	Whole-bird rinse Sponging

* m/M values available

E. coli Workshop

1. From the species below, select those that are covered by the *E. coli* testing regulations (§310.25 and §381.94).

_____ Cattle
_____ Chickens
_____ Ducks
_____ Emus
_____ Geese
_____ Goats
_____ Guineas
_____ Horses
_____ Mules
_____ Ostriches
_____ Rabbits
_____ Rheas
_____ Sheep
_____ Squab
_____ Swine
_____ Turkeys

2. In the left column of species, enter the matching letter for the regulatory sample sites listed in the right column.

_____ Cattle
_____ Goats
_____ Hide on calves
_____ Hide on Sheep
_____ Horses
_____ Swine
_____ Turkeys

A. Flank, brisket, rump
B. Ham, belly, jowls
C. Back and thigh
D. Inside flank, brisket, rump

3. Match the species and sampling technique in the left column to the type of records, shown in the right column, that the establishment must keep.

_____ Cattle, excision	A. m/M Criteria
_____ Cattle, sponge	B. Statistical Process Control
_____ Chickens, whole-bird rinse	
_____ Ducks, whole-bird rinse	
_____ Geese, sponge	
_____ Geese, whole-bird rinse	
_____ Goats, sponge	
_____ Guineas, whole-bird rinse	
_____ Horses, sponge	
_____ Hide on calves, excision	
_____ Hide on calves, sponge	
_____ Mules, sponge	
_____ Sheep, sponge	
_____ Swine, sponge	
_____ Swine, excision	
_____ Turkeys, sponge	
_____ Turkeys, whole-bird rinse	

4. Describe how to perform procedure 05A02 in detail.

5. On May 27, 2003, you must conduct an 05A02 procedure at P-42.

From ISP:

05A02	The establishment collects samples from the type of livestock or poultry it slaughters in greatest numbers; selects carcasses randomly; selects carcass samples at required location in process, and by procedure specified in regulation.	310.25(a) or 381.94(a) Directive 5000.1 Part 4, Par. III	Observe sample collection and review procedures and records. Make determinations about compliance with regulatory requirements. Document failure(s) to comply with regulatory requirements on NR and, when appropriate, take other actions consistent with applicable directive(s).

SCENARIO:

From the random sample collection times provided you by the QA technician at the beginning of the shift, you decide to observe the second *E. coli* sample collection of the day. You observe the technician putting on sterile gloves and randomly collecting one whole, untrimmed carcass at the end of the drip line. Following the procedure, he changes sterile gloves, aseptically sponges two sites (the back and the thigh) of the selected turkey carcass, following the guidelines for proper handling of the sponge. You follow him to the in-house microbiology laboratory where a qualified microbiology technician is waiting.

You discuss the testing procedure used in the on-site lab with the lab technician. She tells you that the analysis is completed using a test method she found in a peer-reviewed microbiology journal two years ago. She says she has memorized the technique and does not need to refer to the instructions in the article as she analyzes the sample. She does have a copy of the *E. coli* test procedure in her files and shares it with you.

Finally, you check the company's process control charts. There is a moving window of the thirteen most recent tests.

INSTRUCTIONS:

1. Using the sample *E.coli* written procedure, records, and the *E. coli* Other Compliance Checklist provided, determine whether the establishment is in compliance.

2. If regulatory requirements are not met, document the noncompliance on the Noncompliance Record. Assume that the next NR is the 29th one in 2003.

BEST AND SAFEST POULTRY COMPANY
P-42
9460 ÉTOUFFÉE Lane
Safeville, LA

E. COLI SPECIMEN COLLECTION PROCEDURE

This is a one-shift, one-line traditional plant that slaughters young turkeys. There is one chilling system and one cut-up line.

Each day of operation the Quality Assurance Manager, or his designee, will collect one carcass at the end of the drip line for each 3,000 birds slaughtered. When selecting a bird at the end of the drip line at the random time, the QA Manager, or his designee, will walk up to the selection point and count five birds. He will then select the sixth bird.

Best and Safest's average daily production volume is 10,000 birds. Based on this volume, one random sample will be taken three times during each shift for two days in a row. Four samples will be taken on the third day. Then the three-day cycle begins again. This method is used to take into account the extra birds produced each day.

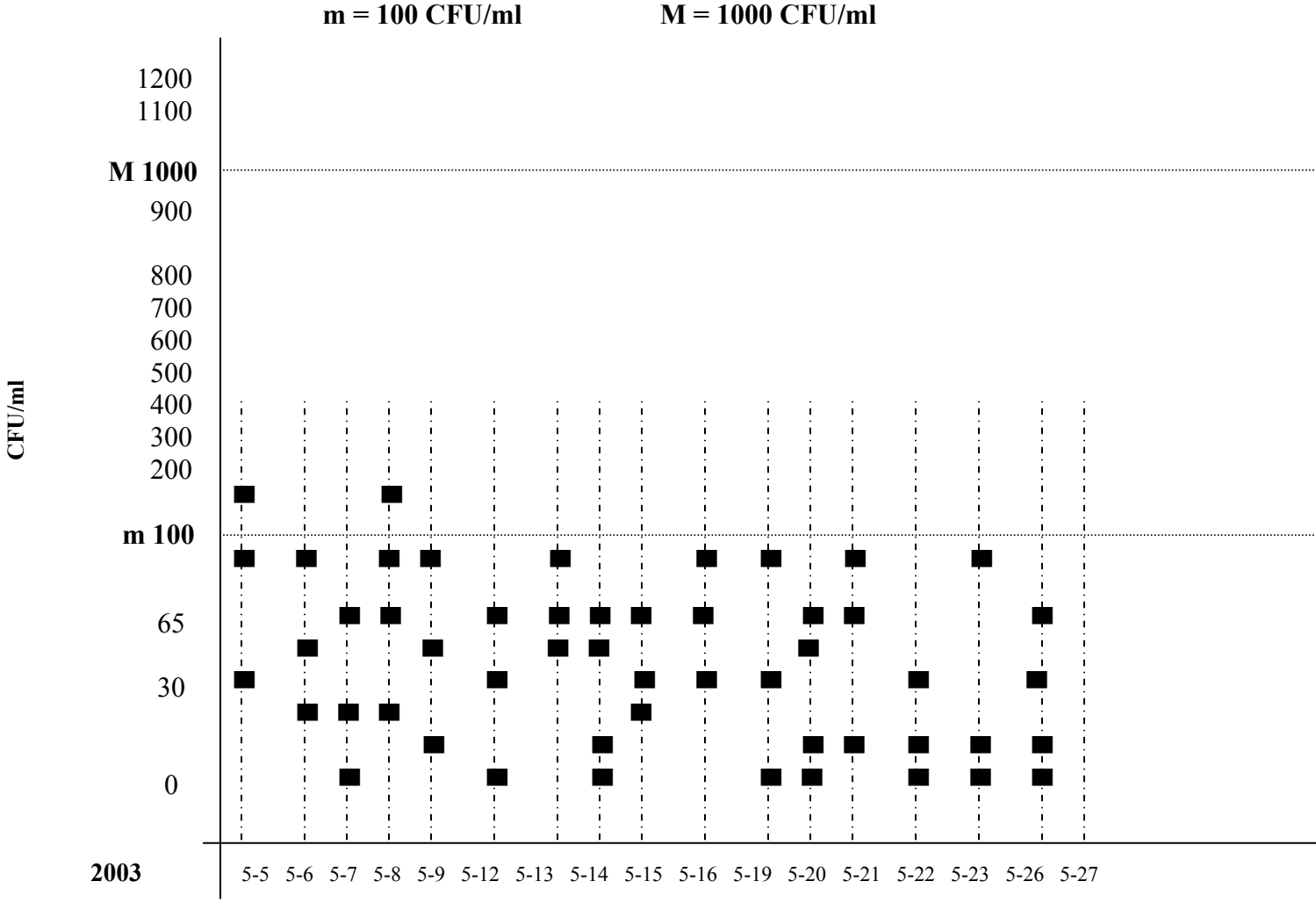
Before the beginning operations, the QA Manager, or his designee, will use a random selection computer program to select the time samples on each shift will be collected. If a random time occurs during a scheduled company break, it will be discarded. Only times within the hours of actual operation will be chosen. These times will be made available to FSIS personnel before operations begin.

Aseptic sampling technique will be used to ensure sample integrity. The sponge method, as outlined in the "Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments," will be followed to ensure sample integrity. Samples will be taken to our own microbiology laboratory for immediate analysis using an AOAC Official Testing Method. In the event our laboratory cannot conduct *E. coli* tests, the QA Manager, or his designee, will immediately refrigerate the sample. At the end of the shift, the refrigerated samples will be sent via overnight Federal Express to the Always Accurate Microbiology Laboratory in Cut and Shoot, TX, for immediate analysis.

Ronald Lynn, Plant Manager *January 27, 1997*

WORKSHOP EXAMPLE ONLY – DO NOT DUPLICATE

E. COLI RESULTS CHART



WORKSHOP EXAMPLE ONLY – DO NOT DUPLICATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE ***E. COLI* CHECKLIST—REGULATORY REQUIREMENTS** **(§ 310.25 OR § 381.94) OTHER COMPLIANCE/NONCOMPLIANCE**		
ESTABLISHMENT NAME	ESTABLISHMENT NO.	PROCESS
REQUIREMENT		YES (√)
1.SAMPLE COLLECTION **a. Livestock or poultry samples** (***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 technique *(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, duck, goose, guinea, or turkey carcass, or sponging a turkey carcass.		
c. Frequency *(paragraph (a) (1) (i) and paragraph (a) (2) (iv), or (a) (2) (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 an 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) (i), (a) (2) (i), and/or (a) (2) (ii)* (1) In selecting carcasses, the establishment is not following its 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 TEST RESULTS *(paragraph (a) (1) (iii) and (a) (4)* a. The establishment's process control chart or tables 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 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)*	
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 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 Form 5000-4

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD**		TYPE OF NONCOMPLIANCE ☐ Food Safety ☐ Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (*Name and Title)*		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATION(S)		

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER
8. ISP Code			

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☐ SSOP	☐Monitoring	☐Corrective Action	☐Recordkeeping	☐Implementation
	B. ☐ HACCP	☐Monitoring	☐Corrective Action	☐Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐Economic	☐Misbranding	☐Protocol	
D. ☐ FACILITY		☐Lighting	☐Structural	☐Outside Premises	☐Product Based
E. ☐ E. COLI		☐Other			

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

FSIS Form 5400-4 ORIGINAL – Establishment

☐ Attachment

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD CONTINUATION SHEET**	1. Date	2. Record No.	3. Establishment No.

4. To (*Name and Title*)

5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Establishment Procedure/Plan | HACCP | SSOP | OTHER

8. ISP Code	9. Noncompliance Indicator

10. Description of Noncompliance:

11. Signature of Inspection Program Employee	12. Date

FSIS FORM 5400-4a (9/97) **ORIGINAL - Establishment**