

Procedure 05A02

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

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. 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.

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.

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

- Excision
- Sponging
- Whole-bird rinse

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	Swine	Turkeys
	Equine	Ducks
	Geese	Geese
	Goats	Guineas
	Sheep	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 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.

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

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.

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

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 and it must be followed.

2. SAMPLE ANALYSIS

a. The laboratory analyzing the samples is not using an AOAC Official Method or another method that meets the criteria in paragraph (a) (3).

Establishments must use an AOAC Official Method or another method 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 the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

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/cm² 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.

They are also required to keep a table or a chart of the results for at least the most recent 13 test results. Establishments must keep records of *E. coli* test results for one year. Charts or tables must express the results in the proper units according to the method of sampling.

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.

If the Agency does not have performance criteria published for the species being sampled or for the sampling technique being used, the establishment must use statistical process control values to document *E. coli* test results.

Example: 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.

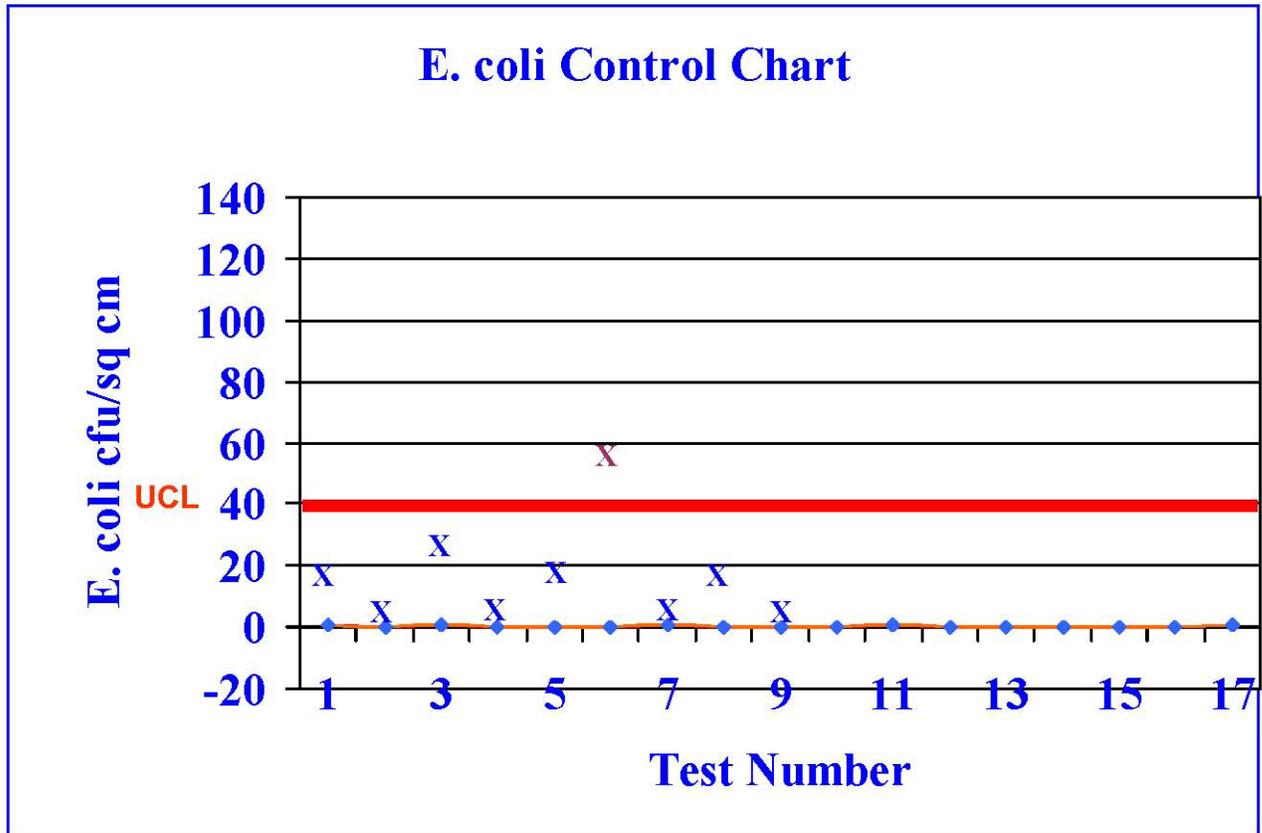
Statistical process control, used when the regulations do not cite performance criteria, begins when the plant conducts a series of preliminary generic *E. coli* tests during its own slaughter operations. They chart the results in cfu/cm² or cfu/ml to determine the typical range of generic *E. coli* counts found at their establishment under normal circumstances. After a company collects test results long enough to believe they have a true picture of their performance, they set an 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 test number 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.



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 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.

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).

If the Agency does have performance criteria published for the species being slaughtered and the sampling technique, the establishment must use m/M values from the regulations to document E. coli test results. Results fall into one of three categories: acceptable, marginal (represented by “m”), and unacceptable (represented by “M”).

If the test result of the most recent sample 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.

The m/M values taken from the regulations are applied to a moving window of the last 13 documented test 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.

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

Species	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/cm²
- Unacceptable if it is above 100 cfu/cm²

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.

05A02 - 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 (NR).

FSIS E. coli criteria are guidelines, not regulatory standards. FSIS does not use company test results to take regulatory action. No NR will be written. 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.