

## Module 8: *E. coli*—Basic and Other Compliance/Noncompliance

You learned earlier that all establishments must have an *E. coli* testing program. They must collect and test samples for generic *E. coli*, specifically *E. coli*, Biotype I, a nonpathogenic bacteria.

In March 1997, an FSIS *E. coli* Special Team began visiting plants to determine whether they were in compliance with the basic regulatory requirements for *E. coli* testing. After HACCP training, FSIS in-plant inspection personnel will be responsible for ensuring compliance with the regulatory requirements for *E. coli*.

So, let's talk about the *E. coli* rule and your responsibility for verifying, documenting, and enforcing the regulatory requirements.

We'll begin by saying that determining whether the *E. coli* requirements are met by an establishment is divided into two parts: "basic" compliance or noncompliance and "other" compliance or noncompliance. Basic compliance addresses certain regulatory requirements the establishment must meet, whereas, other compliance is concerned with the actual execution of the requirements.

We'll get more specific. Let's talk about basic compliance or noncompliance. The final rule stipulates three basic regulatory requirements in all slaughter establishments. First, the establishment must have a written *E. coli* specimen collection procedure. Just like the written procedures for SSOPs and for HACCP plans, the regulation specifies the type of information the *E. coli* written procedure must contain. Specifically, the regulation requires that the procedure identify an establishment employee designated to collect *E. coli* samples, the location and technique of sampling, how plant employees will achieve sample randomness, and how *E. coli* samples will be handled to ensure sample integrity. If the plant doesn't have written sample collection procedures, or if one or more of the elements of the written procedure is missing, basic noncompliance exists.

The second basic regulatory requirement is that the establishment must collect samples for *E. coli* testing from the species it slaughters in greatest number. If the plant isn't sampling and testing for generic *E. coli* basic noncompliance exists.

The third basic regulatory requirement is that the establishment must record the *E. coli* test results on a process control chart or table. If the plant isn't recording and evaluating sampling results, basic noncompliance exists.

When you perform procedure 05A01 you'll be determining establishment compliance or noncompliance with *E. coli* basic requirements. To make your job a little easier you'll be able to use a checklist of the basic requirements as a memory-jogger for the procedure. A copy of this form is in Module 8 of your notebook. You'll get a chance to practice using the form in a workshop a little later.

So, what happens if you conduct procedure 05A01 and find noncompliance with the basic regulatory requirements? First, you must withhold inspection of the slaughter operation and inform plant management that you're withholding inspection. Then

document the noncompliance on a Noncompliance Record. Recall that you won't check a trend indicator on the NR for a basic noncompliance. A copy of the NR must be given to management as soon as possible, and no later than the end of the tour of duty. If you withhold inspection you must notify the establishment right away. Notify the District Office and, additionally, you must send a copy of the NR to the District Office.

If the plant can make immediate corrections, especially for a simple omission like forgetting to enter the name of an employee designated to collect samples in the written procedure, the IIC is authorized to allow operations to continue. The plant must respond verbally or in writing by completing the plant management immediate action and further planned action blocks on the NR.

Once notified, if plant management doesn't take immediate action to return to compliance the next stage of enforcement begins. The District Manager will have a Compliance Officer visit the plant to initiate and develop an investigative case file. The District Manager, will initiate additional appropriate in-plant regulatory action.

Now, let's talk about the second part of the *E. coli* requirements, called "other" requirements. Other requirements are met if the plant successfully executes the activities addressed in the written procedure, analyzes samples, and keeps records of test results. When a PBIS procedure is scheduled, inspection personnel will perform procedure 05A02 to determine compliance or noncompliance with "other" requirements of the *E. coli* rule. This means you'll review plant sample collection procedures, observe collection, and review records of test results.

For example, consider the first requirement of having a written specimen collection procedure. "Other" noncompliance exists if specifications of the written procedure aren't executed; namely: if the establishment isn't collecting samples at the location in the slaughter process required by the regulations; if the establishment isn't collecting samples in the appropriate manner, that is, sponging, excision, or whole bird rinsing; if the establishment isn't collecting samples at the required frequency; and, lastly, if the establishment isn't sampling randomly.

The second topic under "other" requirements is the analysis of samples. The plant must have *E. coli* samples analyzed using an AOAC Official Method or another method that has been approved and published by a scientific body. The last area of the "other" requirements deals with plant records. The establishment must keep the proper records for *E. coli* test results. The establishment's process control chart or table must show at least the most recent thirteen test results. The results of the tests must be expressed in colony forming units per square centimeter when excision tests are used for cattle and swine or sponge tests are used for cattle, swine, or turkeys. *E. coli* test results must be expressed in colony forming units per milliliter when the whole bird rinse method is used. Finally, the establishment must retain records of test results for twelve months. When evaluating test results establishments using excision sampling in cattle and swine or the whole bird rinse in chickens must use little m and big M to evaluate their test results. All other sampling techniques must be recorded using statistical process control.

The *E. coli* Testing Checklist for Other Compliance/Noncompliance is a form that'll be available for use in the field. Much like the Basic Checklist, it'll allow you to consider specific "other" requirements and make individual determinations about compliance.

Documentation must be completed each time you identify "other" noncompliance. Advise the establishment management of the findings and complete a Noncompliance Record. For "other" noncompliance, always mark the trend "other" on the NR. As soon as possible, and, 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.

Enforcement action might be necessary if the establishment repeatedly fails to implement appropriate immediate action or further planned action in response to "other" noncompliance. To start action the IIC should notify the District Office. The District Office will assign a Compliance Officer to the case. The Compliance Officer will work with you in the plant to collect evidence and develop a case file. The District Manager will work with the Compliance Officer to take further enforcement action when necessary. As with basic noncompliance, decisions about further enforcement action for "other" noncompliance will be made on a case-by-case basis.