

Module 9b: Other Compliance/Noncompliance—HACCP Systems

Industry is responsible for developing, implementing, and maintaining effective HACCP systems to ensure food safety.

The FSIS role will be one of regulatory oversight. Industry will be held accountable for maintaining adequate HACCP systems.

Inspection personnel will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the regulatory requirements. The various Agency verification activities may include:

Reviewing the HACCP plan;

Reviewing the CCP records;

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

Reviewing the critical limits;

Reviewing other records pertaining to the HACCP plan or system;

Direct observation or measurement at a CCP;

Sample collection and analysis to determine the product meets all safety standards; or

On-site observations and record review.

As stated earlier, you will review an establishment's HACCP plan upon initial implementation, or anytime it's changed upon reassessment, to determine its compliance with regulatory requirements. This is the basic compliance/noncompliance component of the regulatory oversight model.

After the basic compliance check of the HACCP plan, you will focus on the day-to-day or ongoing operation of the establishment's HACCP system. Determinations will be made about the HACCP system including whether the system prevents the production or shipment of adulterated product. This is the "other requirements" compliance/noncompliance component of the regulatory oversight model.

There are only two "other requirements" procedures for each HACCP activity: those ending in 01 and in 02. In other words, procedure 03B01 is the same as procedure 03C01, 03D01, etc. Likewise, procedure 03B02 is the same as procedure 03C02, 03D02, and so forth. There are nine specific processes for HACCP plans listed in regulations. The nine categories have been given letter designations in the procedure codes. For example, 03C codes are for HACCP plans for raw not ground products, 03D codes are for HACCP plans for thermally processed/commercially sterile products. The identical 01 or 02 procedure is performed on each type of HACCP plan in the establishment.

The purpose of these procedures is to determine if the establishment meets the five features or requirements. The five requirements are monitoring, verification, recordkeeping, corrective actions, and reassessment.

You will be routinely verifying that the plant has met monitoring, verification, and recordkeeping requirements. When you find any deviation, you will also verify that corrective action and reassessment requirements have been met for every deviation.

Let's refresh because we're at the foundation of inspection under HACCP. There are five regulatory requirements—monitoring, verification, recordkeeping, corrective action, and reassessment. These will be verified under procedures 01 and 02.

Now, let's take a closer look at the 01 and 02 procedures. What they have in common are a component for review and observation, and a component of recordkeeping. Both 01 and 02 can be used to verify each of the five requirements.

So what's the difference between the 01 and 02 procedures?

The 01 procedure is for reviewing a random sample of the regulatory requirements in operation. Using the review and observation and/or recordkeeping component, any combination of the requirements can be randomly verified. It would be equally appropriate to focus on one of the requirements specifically while performing 01. For example, you may decide to observe a plant employee measuring a critical limit and recording the result. You may then measure the critical limit and compare your finding with the limit that the employee recorded. You may also review CCP records for a different lot or lots of product and/or calibration records before considering the procedure complete.

The 02 procedure looks at an entire lot or shipment of product. But 02 is *not* random. It still uses the component of review and observation and/or the component of recordkeeping, but for the 02 procedure you will verify *all* of the requirements. You will determine that the establishment is following the HACCP plan, that establishment personnel perform tasks in the plan, that corrective actions are taken, and that pre-shipment review is done for a given lot or shipment. Because the 02 procedure looks at the entire lot or shipment, it determines if the HACCP plan prevented distribution of adulterated product.

The 02 procedure is not considered complete until after you have verified the establishment's pre-shipment review. Therefore, performing the 02 procedure may take some time depending on the process.

You remember that the 01 procedure is for reviewing a random sample of the HACCP regulatory requirements. What if noncompliance is found while performing an 01 procedure? You document noncompliance on a noncompliance report, complete the procedure, then perform the associated 02 procedure. You do this *any time* noncompliance is found on 01.

So far, you've learned there are only two procedures, 01 and 02. You've learned they both have a component for review and observation, and a component for recordkeeping. You've learned they are different because 01 is a random sample of HACCP requirements, while 02 covers all five requirements for an entire given lot or shipment. And you've learned that the five requirements are monitoring, verification, recordkeeping, corrective action, and reassessment.

Now let's explore just what is meant by the component of review and observation and the component of recordkeeping.

The component of review and observation includes observing activities occurring in production areas and examining production documents. It includes performing on-site tests such as taking temperatures of product after cooking, temperatures of coolers or carcasses in coolers, or temperatures of chill water to determine if the CCP as defined in the plan is under control, and comparing inspection results to HACCP plan records. And it includes directly observing an establishment employee performing an activity such as taking temperatures, calibrating monitoring equipment, or taking corrective action to determine if the plant is following the HACCP plan and recording measurements accurately and promptly.

The recordkeeping component should be conducted in an organized manner. Start with an ISP guide procedures, FSIS Directive, and/or Regulation. Then proceed to select and assemble appropriate records. And then you are ready to determine if requirements have been met.

[graphic for above]

When you select records, determine the type and number of records based on the procedure you are doing and the number of available records. For the 02 procedure, select complete record sets for a specific production lot. If a problem is found which may also affect other production lots, then also select records for those other lots to determine if the problem is isolated or represents a pattern. Do not select records that have already been examined, except the 02 entire lot procedure could repeat some records reviewed under the 01 random review.

Thorough record review is critical to the overall effectiveness of FSIS verification activities. Records may be used to show the establishment is not in compliance with regulations and to support regulatory action. We'll have more specifics on recordkeeping later.

[facilitator does review before proceeding]

Recalling the five requirements are monitoring, verification, recordkeeping, corrective actions and reassessment, let's look at your responsibility for the 01 procedure components and the 02 procedures for each of the five requirements.

If you're not clear on the five requirements, procedure 01, procedure 02 and the two procedure components, review them now. They form the basis for inspection responsibilities.

[pause]

Monitoring is the first of the five requirements we'll examine. Establishments are required by Directive 5000.1 to monitor critical control points to ensure compliance with critical limits, and provide a recordkeeping system containing actual values obtained during monitoring. These requirements are based on sections 417.2 and 417.5 of the regulation. We'll look at the two components for both the 01 and the 02 procedures.

The review and observation component determines if the establishment's monitoring is performed as stated in it's HACCP plan. You'll need to be very familiar with the plan to know the method and frequency of measuring critical limits. Then you'll directly observe plant employees performing the tasks as stated in the plan. For example, measuring the internal product temperature from specified locations in the cooking unit and recording the lowest value. Or for example, properly measuring the pH of a mixture of the liquids and solids portion of a product. You will determine whether plant employees monitoring as stated in the HACCP plan, doing it at the stated frequency, and whether they are accurately and promptly recording their monitoring results. Observation also includes your own measurements to see if your values match those recorded by the establishment.

Now, let's look at the recordkeeping component of monitoring. You will determine whether plant employees record their observations, tests or measurements at the required frequency, whether all required data has been recorded, the accuracy of the data, and whether critical limits have been met and corrective actions taken.

Remember, you can do the review and observation and/or recordkeeping component to determine if the monitoring requirements have been met.

Remember also, if the plant finds a deviation, the corrective action taken by the establishment must meet the HACCP regulatory requirements. This should be a trigger mechanism for you to verify the corrective action requirement.

Finally, remember that if you find noncompliance, mark the "Monitoring" trend indicator on the NR and PS.

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Verification is the second of the five requirements we'll examine. Establishments are required by Directive 5000.1 to state their ongoing verification activities, including

frequency, and to maintain related records such as calibration of instruments and actions taken in response to a deviation from a critical limit. These requirements are based on sections 417.2 through 417.5 of the regulation. In addition, sections 310.25 and 318.94 require that plants that have substituted alternative *E. coli* sampling frequencies must include the alternative in its verification procedures.

The verification activities listed by the establishment in its HACCP plan will dictate what you will do when you perform the procedures for this requirement. Again, there are review and observation and also recordkeeping components for both the 01 and 02 procedures.

For the review and observation component, you determine if the establishment's employees are performing verification as stated in the plan, at the frequency stated in the plan, and recording results promptly. Some verification activities might be product testing and process monitoring equipment calibration if stated in the plan.

For the recordkeeping component, you determine whether establishment employees are doing product testing, record reviews, other audits, and calibrations at specified frequencies. You will also determine if corrective action is taken when necessary.

Remember, you can do the review and observation and/or recordkeeping component to determine if the verification requirements have been met.

But here's an important point about the 01 procedure for verification. It's about alternate sampling for *E. coli*. If the establishment has an alternate sampling plan for *E. coli*, it will be verified under the 01 procedure. For example, an establishment's beef slaughter HACCP plan might test fewer than the number of carcasses required by FSIS based on sanitary dressing critical control point sampling results exceeding the FSIS requirement. The establishment's HACCP plan would include a verification activity for the *E. coli* sampling.

Remember, just like with monitoring, if a plant employee finds a deviation, the corrective action taken by the establishment must meet the HACCP regulatory requirements. This should be a trigger mechanism for you to verify the corrective action requirement.

Finally, remember that if you find noncompliance, mark the "Verification" trend indicator on the NR and PS.

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Recordkeeping is the third of the five requirements. Records include written and electronic data. You will be reviewing establishment records that document their monitoring of the critical limits for critical control points, any corrective actions taken, and the establishment's verification activities.

Recordkeeping is a very serious matter, and has grave implications if records are falsified or not properly maintained.

When you verify the recordkeeping requirement of the establishment's HACCP plan, you will only perform the recordkeeping component.

Establishments have several recordkeeping requirements as outlined by Directive 5000.1. They must have scientific, technical, or regulatory documentation to support the critical control points, critical limits, monitoring procedures, verification procedures, and frequencies in their HACCP plans. They must identify product through production lots, codes, bar codes or names. They must ensure the records are authentic and timely including the date, time, and initials of the establishment employee. They must ensure the integrity of records, including computer records. They must review records for a production lot before shipment. And they must make records available and retain them for certain periods. These requirements are based on section 417.5 of the regulation.

You remember that earlier you learned you will see much variety in the HACCP plans where you work. Recordkeeping requirements ensure documentation will be available to document the decisionmaking associated with the selection and development of CCPs and critical limits, including references to the basis (scientific or technical and/or regulatory). For example, the establishment may have documentation from a process authority that a certain cooling curve in Regulation 318.17 is equivalent to the FSIS cooling curve for inhibiting microbial growth. You would then use the times and temperatures of that cooling curve as stated in the HACCP plan to determine compliance.

Sometimes you may have questions about various processes you see in HACCP plans. You'll learn later about getting technical assistance.

Now we'll look at the 01 and the 02 procedures for the recordkeeping component. Because the 01 procedure is performed on a random basis, you will verify the HACCP support, product identification, record authenticity, data integrity, and record retention and availability requirements while performing the 01 procedure. For the 02 procedure, you'll verify only the pre-shipment and data integrity requirements.

Remember just like before, the corrective action taken by the establishment must meet the HACCP regulatory requirements. If the plant finds a deviation, this should be a trigger mechanism for you to verify the corrective action requirement.

Finally, remember that if you find noncompliance, mark the "Recordkeeping" trend indicator on the NR and PS.

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Corrective action is the fourth of the five requirements. Here, you may see two general types of corrective actions taken by the establishment: corrective action based on deviation from a critical limit, and corrective action based on unforeseen hazards.

More often, you'll see corrective action based on deviation from a critical limit. The establishment has thought ahead when it developed the HACCP plan, and stated its corrective actions for deviations from critical limits. Establishments are required by Directive 5000.1 to do several things. They must identify in their HACCP plan the establishment personnel responsible for taking corrective action. They must incorporate corrective actions into their HACCP plans and then do what they say. They must take *and document* procedures to identify and eliminate the cause of the deviation, procedures to bring the critical control point under control, procedures to prevent recurrence, and procedures to prevent distribution of adulterated product. And they must maintain records that document corrective actions. These requirements are based on sections 417.2, 417.3, and 417.5 of the regulation.

The review and observation component that you do for corrective action for deviations might be on-site tests or observations to verify the establishment has brought the critical control point back under control. Or, it might be observing the plant's procedures for segregating affected product.

The recordkeeping component that you do for corrective action for deviations will be to determine if the corrective actions conform to all four regulatory requirements of section 417.3.

Here's an example of how an establishment might meet the four regulatory requirements. The critical limit for water pressure in a swine slaughter establishment is 200 psi, monitored hourly. The pressure dropped below 200 psi. The establishment documentation may be like this.

Monitoring records showed the pressure was 190 psi. The carcass chain was stopped until pressure returned to 200 psi, and an alarm was installed. This is the requirement to identify and eliminate.

Monitoring was increased to 15-minute intervals and the alarm tested. This is the requirement to return the critical control point to control after taking action.

Verification included weekly testing of the alarm. And the HACCP plan was updated. This is the requirement that measures are taken to prevent recurrence.

The carcasses that went through the final wash cabinet after the last acceptable pressure monitoring check were segregated and treated with an antibacterial spray. This is the requirement that procedures are done to prevent distribution of adulterated product.

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So far we've focused on corrective actions based on deviation from a critical limit. Corrective action is defined differently for unforeseen hazards.

Occasionally, you'll see the establishment has found an unforeseen hazard. Establishments are required by Directive 5000.1 to take action when a deviation occurs that is not covered by corrective actions in its HACCP plan. The establishment must segregate and hold the product until a review determines acceptability of the product for distribution, must ensure that no adulterated product is distributed, must do reassessment to determine if the unforeseen hazard should be included in the HACCP plan, and must document any corrective action it takes for the unforeseen hazard. These requirements are based on sections 417.3 and 417.5 of the regulation.

For the review and observation component, you will check the adequacy of the establishment's procedures in response to a deviation from a critical limit that did not have specific corrective actions detailed in the HACCP plan or an a unforeseen hazard. For example, you may observe the plant's procedure for holding and segregating affected product to assure that adulterated product does not enter commerce.

For the recordkeeping component, you will verify that the procedures the establishment uses to segregate and hold the affected product and any corrective action taken to ensure that adulterated product was not shipped is documented.

Finally, remember that if you find noncompliance, mark the "Corrective Actions" trend indicator on the NR and PS.

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Well, we've reached the fifth and last requirement, which is plan reassessment. Establishments are required by Directive 5000.1 to reassess their HACCP plans when a deviation is not covered by a stated corrective action, when an unforeseen hazard deviation occurs, when there is a second consecutive positive *Salmonella* result for raw meat or poultry, or when any change affects the hazard analysis. The establishment must modify its HACCP plan any time reassessment shows the plan no longer meets requirements. And the individual who reassesses and modifies the plan must be trained. These requirements are based on sections 417.2, 417.3, 417.4, and 417.7 of the regulation, plus sections 310.25 and 381.94.

The only time you verify the establishment's reassessment is when it is triggered by an unforeseen hazard deviation or a second positive *Salmonella* result. If an unforeseen hazard is reasonably likely to occur, the HACCP plan must be modified. Otherwise not. If the plan *is* reassessed, it does *not* have to be documented. Therefore, there is no recordkeeping component. For the review and observation component for either the 01 or 02 procedure, you may observe the establishment's reassessment of the plan.

The District Office will give you instructions about positive *Salmonella* results on a case-by-case basis.

When you look at the establishment's reassessment due to its hazard analysis, it could result from changes like raw materials, formulation, packaging, or equipment.

When reassessment triggers the establishment to modify its HACCP plan, you will always perform 03A01, the basic compliance checks procedure.

The last point about reassessment deals with the person doing it. Although the individual must meet training requirements, the establishment is not required to furnish evidence of the training.

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A few final comments about the five regulatory requirements.

You will verify all five requirements. Three of the five can always be done. Establishments must continually meet monitoring, verification, and recordkeeping requirements. Therefore, you can always perform procedures for these. Establishments only meet requirements for corrective actions and reassessment when there is a reason. If there are no deviations, unforeseen hazards, or positive *Salmonella* results, there are no requirements to meet and it's not possible for you to do a procedure.

Remember that HACCP is a system, and we must allow the system to work. That's the reason for having the both the random 01 procedure and the production lot 02 procedure to determine regulatory compliance. Looking at the system is the reason you proceed to the 02 procedure after finding noncompliance with the 01 procedure.

And lastly, remember the 02 production lot procedure cannot be completed until pre-shipment review has been done by the establishment and the plant reviewer has signed and dated the records. This means there could be a short time or a long time elapsed between finding a procedure 01 noncompliance, and then completing the resulting 02 procedure. For example, you could find an 01 noncompliance for ground beef and complete the 02 procedure by the end of the next shift. Or, you could find an 01 noncompliance for dry cured ham but need several days, or even weeks, to complete the 02 procedure.

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So, what's next after verifying the five regulatory requirements? You will determine if there is noncompliance. This is shown in block 8 of the regulatory process model. And if there *is* noncompliance, you will determine if there is a system failure as shown in block 9.

To determine noncompliance, use what you know for a fact and what is reasonable to assume. You need to assess your observations, analyze the facts, decide what performance standards or regulatory requirements apply, and then make your determination.

Let's use an example.

Suppose you are verifying the critical control point monitoring requirement by performing the review and observation component of the O1 procedure. The establishment's plan states the critical control point will be monitored every half-hour by a QC technician. If critical limit is exceeded, the QC technician will notify the QA manager, who will initiate corrective action. The QC technician will record the action.

What you find, as you do the O1 procedure, is the critical limit was exceeded. The previous recorded value was OK. It was taken 20 minutes ago. What do you do?

You should allow the establishment's HACCP plan to work. So therefore, part of the O1 procedure is to return after the next monitoring check to observe the QC technician's findings and actions. It's true that when the critical limit is exceeded, the establishment is not meeting the standard it defined in its plan. However, if the QC technician and the QA supervisor take the corrective actions described in the plan, there is no noncompliance.

Remember, the establishment has time to institute corrective action prior to signing pre-shipment documents. The pre-shipment review is the final step in its HACCP system. We must allow the system to work.

So, just what is noncompliance? Noncompliance is the failure to meet any HACCP regulatory requirement. That is monitoring, verification, recordkeeping, corrective action, and reassessment. Noncompliance exists when either the establishment is not implementing its HACCP plan, or when its HACCP plan fails to prevent the production and shipment of adulterated product.

In our example, the monitoring requirement was met and corrective action taken, so there was no noncompliance. Now suppose the QC technician did not find the deviation during monitoring, but the QA manager did find it during verification? Here, even though the deviation was ultimately found, the monitoring requirement itself was not met and therefore there *is* noncompliance.

Now, let's suppose a final step. Let's say the QC technician did not find the deviation during monitoring, the QA manager did not find the deviation during verification, but the HACCP supervisor *did* find the deviation during pre-shipment and took the appropriate action. What do you decide? Once again, even though the deviation was ultimately found and properly acted upon, the establishment failed to meet the monitoring and verification requirements, and therefore there *is* noncompliance.

The next question in our regulatory process model is: "Is there a system failure?"

When you find noncompliance, you will need to determine if the system has failed. For HACCP, the regulations 417 define a system failure as an inadequate system.

So to determine if the HACCP system is inadequate, the questions you should answer are:

Question 1—Did the establishment review the records associated with production of the product? This review should have included determination that all critical limits were met and, if appropriate, corrective actions were taken, including proper disposition of product.

If the establishment has not performed the pre-shipment review, then it has not met the regulatory requirements (417.5(c)). Therefore, you are unable to make the determination that the establishment is not producing adulterated product, and therefore the HACCP system is inadequate.

The determination of an inadequate system in this case could only be determined by performing the 02 procedure.

Question 2—Was adulterated product produced or shipped?

That is, the IIC has determined that the HACCP system did not prevent the production and distribution of adulterated product. That is, the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per 417.3. If you are able to make this determination, and the establishment has performed its pre-shipment review, then the HACCP system is inadequate.

The determination of an inadequate system in this case could only be determined by performing the 02 procedure. Although, keep in mind, you could have performed the 02 procedure in response to noncompliance found during the 01 procedure.

Question 3—Is there noncompliance with the same root cause?

That is, are there the same and/or related noncompliance occurring due to the negligence, ineffective method, or incomplete execution by the plant? (FSIS Directive 5000.1 III. C. 2.) If yes, it is possible that you have an inadequate system. There is still no magic number to determine when a systems failure exists due to the same and/or related noncompliance. The NRs should document ongoing failures of the plant's maintenance or implementation of the HACCP plan and/or execution of effective immediate and further planned actions to bring themselves back into regulatory compliance. Professional analysis must be used when making this determination. You will want to be certain that your documentation made the linkage to the previous noncompliance. You might look at previous NRs noncompliance trend indicators to help make this linkage. If you are able to make this determination and the documentation supports it, then you have an inadequate system.

Noncompliance that are failures to comply with the regulatory requirements, such as plan documentation, monitoring procedures and methods, or verification procedures and methods that are not determined to be an inadequate system will be documented on an

NR with the appropriate trend indicator marked. The 01 procedure is specifically designed to determine if regulatory requirements are met. The appropriate noncompliance trend indicator would be marked on the NR, and if the same and/or related noncompliance is occurring due to the negligence, ineffective method, or incomplete execution by the plant, it is possible that these may lead to the determination of an inadequate system.

Documenting trends could also occur while performing the 02 procedure. The inspector will document the trend(s) when an establishment fails to meet a HACCP regulatory requirement, but it makes this determination and performs any necessary corrective actions prior to shipping the product. For example, if while performing the 02 procedure, inspection personnel determine that the establishment had a deviation from a critical limit at monitoring, but the establishment discovered the deviation during its verification and took the corrective action according to its plan, then the inspector would document this as a noncompliance with the monitoring requirement. Because in this case the system has in fact worked, you might be asking why we are documenting this on an NR. We are documenting on the NR as a means of documenting the trend.

The determination of an inadequate system in this case could be determined by performing the 01 or 02 procedure.

And question 4—Has the establishment met the basic regulatory requirements? That is, if the establishment is not implementing all or some of their program, then it has not met the basic regulatory requirements. For example, if an establishment is not maintaining any records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify their HACCP plan when it no longer meets the requirements—then the establishment has not met the regulatory requirements. Therefore, you are unable to make the determination that the establishment is not producing adulterated product, and therefore the HACCP system is inadequate. In these cases the HACCP system would be considered inadequate for not meeting the Basic regulatory requirements. This noncompliance would be documented under the Basic procedure code 03A01.

The determination of an inadequate system in this case could be determined by performing the 01 or 02 procedure.

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If you have determined that there is an inadequate system, you should follow the enforcement action in Part Two of FSIS Directive 5000.1 III. C.1. This action is:

Withhold inspection and notify the establishment. Provide plant management a copy of the NR. Notify the DO of actions taken. The DM will assign a CO who will visit the establishment and initiate a case file. The DM will provide instructions for enforcement actions from this point. (The action is identical to that which is taken if the establishment fails to meet the basic regulatory requirements.)

It is important to reiterate that the inspection personnel are to contact the District Office in cases of a withholding action due to a system failure.

If the inspector is not able to determine that there is a system failure then, the enforcement action is according to Part Three of FSIS Directive 5000.1 III.C. 2.—

That is, take official control action as appropriate; advise establishment management by providing a copy of the NR that documents the noncompliance finding(s); complete documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5); and notify the DO if the establishment does not bring itself into compliance.

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If there is a HACCP system failure involving the production or shipment of adulterated product in which misrepresentation of records is suspected, inspectors must withhold inspection and deal with the adulterated product first, and then deal with the misrepresentation issue. Public health and safety always takes precedence over any other activities.

If, at any time, FSIS inspection personnel suspect that a plant has engaged in any illegal activity (e.g., falsified required records; offered for sale, sold, or transported adulterated or misbranded meat and poultry products in commerce), they will report the alleged violations to the appropriate District Enforcement Operations Official, who will contact a Compliance Officer.

Once the Compliance Officer arrives at the plant, he or she will want to review your Noncompliance Record files to develop a case history. This history will aid the District Manager to either sustain current action or take further regulatory action.

When the Agency proceeds with a case, the case file is presented before an Administrative Law Judge. This person has legal knowledge, but may know next to nothing about how our Agency functions in carrying out the Law. Your documentation is legal evidence and must be written so that legal authorities can understand the seriousness of the noncompliance. Your documentation must support regulatory actions. This is the reason your documentation is so important. The Compliance Officer will go through your documentation looking for linkages or recurring noncompliance to prove that the plant does not have proper control over its processes. The Compliance Officer will stress these points in the case file.

In addition to the documents, the Compliance Officer will take a statement from you. This is important, because it establishes you as a field expert. It allows your thought process to be captured in writing for legal authorities to review and understand without interviewing you at the time of the review. Your statement also demonstrates that you are working within the scope of your employment if later indemnification occurs. Keep in mind that Compliance needs your help to build a case.

Finally, suspension and withdrawal actions are subject to Department and Agency supplementary guidelines and rules of practice. You will receive specific instructions on appropriate in-plant controls on a case-by-case basis from the District Office.