

CHAPTER IV - ENFORCEMENT

I. FSIS Form 5400-4, Noncompliance Record (NR)

A. The NR and NR Continuation Sheet completed in the PBIS Electronic format following the instruction for PBIS 5.1.3.

B. Type of noncompliance

Food Safety

Any 01 - SSOP

Any 03 - HACCP

06D01 – Sanitation Performance

Requirements

Standards

05A01 - micro. sampling for *E. coli*

05A02 - micro. sampling for *E. coli*

05A03 - micro. sampling for *Salmonella*

05B02 - Directed sampling

05C01 - Residue

Other Consumer Protections

Any 04 - Economic/Wholesomeness

05B01 - Economic Sampling- Scheduled

06D02 – Inspection

BLOCK

1. -3. are automatically completed in PBIS 5.1.3.

2. **To (Name and Title)**--Enter the name and title of the responsible establishment official. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a Sanitation SOP regulation noncompliance, always enter the name of the person who signed the Sanitation SOPs. For SPS noncompliance, the CSI should enter the name of the establishment official responsible for responding to the NRs.

3. **Personnel Notified**--Enter the name of the establishment management personnel who was/were notified about the noncompliance.

4. **Relevant Regulations**--Cite the specific regulatory requirements that the establishment did not meet. For example, if the establishment did not take corrective action in response to a deviation from a critical limit, then 417.3 (a) would be entered. Inspection program personnel are to use the drop menus found in PBIS 5.1.3.

5. **Relevant Section/Page of Establishment Procedure/Plan**—Enter the section or page of the establishment's procedure or plan when the noncompliance represents the failure to comply with the written provisions of their procedure or plan. For example, if the monitoring frequency listed in the HACCP plan is hourly, and the establishment performs the procedure every two hours, there is monitoring noncompliance. Inspection program personnel record the section or page of the HACCP plan that lists the monitoring frequency. Place

an “X” in the appropriate box to reference the type of procedure or plan. *E. coli* and alternate processing procedure noncompliance are considered “other.” When the noncompliance is not related to a procedure or plan, enter N/A.

6. **ISP Code**--Enter the code of the procedure performed (refer to: FSIS Directive 5400.5; Attachment 6, Inspection System Procedure Guide for a listing of codes).

7. **Noncompliance Classification Indicators**--Mark the classification trend indicator that best describes the noncompliance. This should be the same classification trend indicator that is circled when inspection program personnel complete the related FSIS Form 5400-2; Procedure Schedule. For basic compliance procedures (01A01, 03A01, and 05A01), no trend indicator is marked.

10. **Description of Noncompliance**—Describe each noncompliance in clear, concise terms, including the exact problem, its location, and the effect on product. For example, if the CSI observes condensation dripping from the ceiling onto exposed product, the description should include the area of the plant where the observation was made, what type of product was being contaminated, and the action taken. If there is a trend of noncompliance developing, and the current NR is linked to previous NRs, the CSI should list the previous NRs with the similar noncompliance from the same cause. The NR should state what corrective actions were proposed, and that these actions were ineffective or not implemented. If this developing trend has been discussed with establishment management, this information should also be documented in this block. If more space is needed to describe noncompliances for procedure codes 01B and 01C, inspection program personnel may use a NR Continuation Sheet.

11. **Signature of Inspection Program Employee**--The IIC or CSI signs the NR after blocks 1 through 10 have been completed.

12 & 13. **Plant Management Response**--The "immediate action" and "further planned action" blocks should be completed. When the establishment elects to respond, the “immediate action” is the action the establishment is taking to correct the noncompliance including appropriate product disposition. The “further planned action” is the action to prevent recurrence. Inspection program personnel should document an oral response by the plant management.

14 & 15. **Signature of Plant Management and Date**--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.

16 & 17. **Verification Signature of Inspection Program Employee and Date** – To indicate that an NR is closed, the IIC or CSI is to sign these lines.

NOTE: The NR can only be closed after inspection program personnel have verified the establishment has brought itself into compliance with the regulatory requirement that was not met and resulted in the issuance of the NR. If the non-compliance necessitates the establishment to take actions as required by 9 CFR 416.15 or 417.3, the NR can only be closed after inspection program personnel have verified that the establishment has met the requirements of 9 CFR 416.15 and 417.3. Remember, the establishment is not required to indicate its corrective and preventive measures on the NR and CSIs may need to verify corrective actions by reviewing establishment records.

B. How can FSIS personnel write a complete and accurate NR?

- Clearly and concisely identify each noncompliance. Be descriptive, specific and thorough, including time and location.
- Explain that the establishment management has received adequate oral and written notification.
- Include:
 - The inspection findings,
 - Any previous corrective actions that were unsuccessful, and
 - Any applicable deadlines.
- Set out the establishment response to previous notification.
- If a regulatory control action is taken, describe the action (e.g., applying a tag to boxes or stopping a line).

C. How is the continuation sheet completed?

In addition to the NR, there is a Continuation Sheet, FSIS Form 5400-4a, that is used only when the inspection program personnel need extra space, or when multiple inspection program personnel conduct verification of pre-operational sanitation inspection procedures in elements 01B and 01C. When using the NR Continuation Sheet for extra space, inspection program personnel can just check the box next to the word "Attachment" in the top right corner of the sheet, and complete blocks 1-3,10,11 and 12.

II. Documentation of SPS Noncompliance

A. What are the general procedures for documenting the SPS verification activities?

The CSI performs ISP procedure 06D01 to verify compliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the CSI finds that the establishment is not meeting the SPS requirements, he or she should document the noncompliance on the NR. If the noncompliance is failure by the establishment to comply with the SPS, the Food Safety block is checked on the NR.

There are four trend indicators associated with procedure 06D01. Those trend indicators are lighting, structural, outside premises, and product based. Only one of these trend indicators can be used for each NR issued. If more than one trend indicator applies, the CSI should use the most appropriate one to describe the noncompliance. If the determination has been made that there is regulatory noncompliance, the CSI should include the regulation citation in Block 6 of the NR.

B. When is the lighting trend indicator used?

The lighting trend indicator is used when there is noncompliance with lighting requirements. If inadequate light causes the quality or intensity of lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, the lighting trend indicator should be marked on the NR. (see Chapter I, Part IV).

NOTE: The CSI should realize that there might be less than perfect situations that do not constitute noncompliance. If one light is inoperable, but its absence does not cause the intensity or quality of the lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, there is no noncompliance.

C. When is the structural trend indicator used?

The structural trend indicator is used when structural regulatory requirements are not met. The CSI should use the structural trend indicator when structural noncompliances are observed, such as holes in the wall, cracks or holes in the floor, or condensation on overheads that create insanitary conditions or could result in product adulteration. (see Chapter I, Part III).

D. When is the outside premises trend indicator used?

The outside premises trend indicator is used when the CSI finds that the regulatory requirements for outside premises are not met. For example, the CSI should use the outside premises trend indicator when he or she observes an accumulation of trash or rubbish outside the establishment that permits harborage and breeding of pests. (see Chapter I, Part II).

E. When is the product based trend indicator used?

The product based trend indicator is used when there is noncompliance involving product that does not result in misbranding, mislabeling, or direct product contamination that is covered by the Sanitation SOPs. For example, the CSI observes product from the previous day's production on a wall before the start of operations that creates an insanitary condition, he or she should use the product based trend indicator. (see Chapter I, Part XII).

F. What actions should be taken when noncompliance with the SPS regulations is observed?

If an establishment has not complied with a sanitation performance standard, and product is not directly contaminated, CSIs need to determine whether the noncompliance requires a regulatory control action to prevent contamination or adulteration of product.

1. If there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately, CSIs will take a regulatory control action such as tagging product or rejecting equipment and complete a NR.

2. If the noncompliance does not need immediate attention, CSIs are to notify the establishment management of the noncompliance and document the finding on a NR.

If an establishment has not complied with a sanitation performance standard, and product is directly contaminated, CSIs will verify that the establishment addresses the noncompliance by meeting the requirements of 9 CFR 416 or 9 CFR 417 as described below. CSIs will write an NR using the appropriate 01 (Sanitation SOP) or 03 (HACCP) ISP procedure code.

1. If direct product contamination occurs, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 416.15. The establishment may need to re-evaluate the effectiveness of its Sanitation SOPs and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

2. If the direct product contamination poses a food safety hazard, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective

actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

III. Documentation of Sanitation SOP Noncompliance

A. What do CSIs document?

The CSI performs the Sanitation SOP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 416.12 – 416.16. When the CSI determines that the establishment does not meet one of these regulatory requirements, he or she should document the noncompliance on an NR, marking the most appropriate trend indicator and the food safety box.

The four trend indicators for Sanitation SOP are:

1. monitoring,
2. implementation,
3. recordkeeping, and
4. corrective actions.

NOTE: Only one trend indicator should be used for each NR issued.

B. When is the monitoring trend indicator used?

The CSI should mark the monitoring trend indicator on the NR when he or she determines that the plant fails to monitor its pre-operational or operational sanitation procedures daily or at the frequency specified in the Sanitation SOP. When the CSI observes contaminated product or contaminated direct contact surfaces that the establishment monitor did not detect, the monitoring trend indicator is used. (see Chapter I, Part XIV).

C. When is the corrective action trend indicator used?

The CSI should mark the corrective action trend indicator when the establishment does not meet the corrective action requirements. This trend indicator should be marked on the NR when the establishment does not take corrective actions to meet the requirements in 9 CFR 416.15. This trend indicator should be used when FSIS determines that the corrective actions taken are not adequate to restore sanitary conditions. It would be the appropriate trend indicator to use if the establishment did not implement measures adequate to prevent recurrence. If the establishment did not implement corrective action to ensure appropriate disposition of contaminated product, this would be the appropriate trend indicator. (see Chapter I, Part XVI).

D. When is the recordkeeping trend indicator used?

The CSI should use the recordkeeping trend indicator when there is noncompliance with 9 CFR 416.16. This trend indicator would be marked when the records are not being maintained daily or retained for the required period of time, or the plan fails to record the results of the monitoring check. This is the appropriate trend indicator to use when the establishment is not documenting the corrective actions taken when FSIS or the establishment determines the Sanitation SOP did not prevent direct contamination or adulteration of product. This trend indicator would also be marked on the NR when the records have not been initialed and dated. (see Chapter I, XVII).

E. When is the implementation trend indicator used?

The CSI uses the implementation trend indicator when he or she finds two regulatory requirements that have not been met during the performance of one procedure. For example, if the CSI is performing the 01C02 procedure and finds that the establishment is not monitoring the operational procedures at the stated frequency and did not initial and date the daily sanitation records, the appropriate trend indicator to use is implementation.

F. What actions do CSIs take when noncompliance with the Sanitation SOPs is observed?

When the CSI is performing the 01B02 or 01C02 Sanitation SOP procedure and observes direct contact surfaces or product that is contaminated, he or she should take a regulatory control action on the equipment or product. He or she should not remove the regulatory control action until the establishment has proposed corrective actions that 1) ensure appropriate disposition of products, 2) restore sanitary conditions, and 3) prevent recurrence of direct contamination or adulteration of products. The CSI documents the noncompliance on the NR. If the CSI is performing the 01B01 or 01C01 Sanitation SOP procedure and observes that the establishment official responsible for the implementation and monitoring of the Sanitation SOP did not initial and date the record, the CSI documents the noncompliance on the NR, although no regulatory control action would be required.

NOTE: If the establishment has found the noncompliance and taken the corrective actions required, there is no noncompliance. The CSI should verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces. If the establishment finds that the responsible individual did not initial and date the record and implemented immediate and further planned actions and records these actions, the CSI should not document this as noncompliance.

G. What actions do CSIs take when noncompliance is found with both SPS and Sanitation SOP regulatory requirements?

If the CSI is performing one of the sanitation procedures (06D01, 01B02, 01C02) and observes noncompliance with the SPS and Sanitation SOP regulatory requirements, all of the findings would be documented under the appropriate Sanitation SOP procedure. If the CSI is performing the 01B02 or 01C02 procedure and only observes noncompliance with the SPS regulations, he or she should document the Sanitation SOP procedure as performed on the Procedure Schedule, and issue a NR under the 06D01 procedure. If the CSI is performing the 06D01 procedure and only observes Sanitation SOP noncompliance, he or she should document the 06D01 procedure as performed and issue a NR for the Sanitation SOP noncompliance using the appropriate procedure (01B02 or 01C02).

IV. HACCP Noncompliance Determinations

A. What is the difference between a deviation from a critical limit and HACCP noncompliance?

A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take actions in accordance with 9 CFR 417.3.

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR part 417, monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

B. What should CSIs consider before making a noncompliance determination?

Before making a determination that there has been noncompliance, consider the following questions:

1. Has the establishment already identified the failure to meet the regulatory requirements or deviations from critical limits?
2. If product is involved, has the establishment ensured product safety?
3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR 417.3 corrective and preventive measures to address the deviations?

4. Is a trend developing (i.e., has the establishment repetitively carried out the actions in 1 through 3 above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

If the answer is no to questions 1, 2, or 3, or yes to question 4, then a noncompliance exists. CSIs will write an NR and perform a HACCP 02 procedure.

If the answer is yes to 1 through 3 and no to question 4, then there is no noncompliance because the establishment has already identified and addressed the situation. The HACCP 01 should be considered performed, and no other action is necessary. Because the establishment's response provides the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an inspection program employee's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

C. What are some situations that CSIs may encounter that will require a determination as to whether there is a noncompliance?

NOTE: For purposes of consistency, all the examples below use a monitoring example. The methodology applies to problems with verification, recordkeeping, reassessment and corrective actions as well.

EXAMPLE 1: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check. The inspector then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by re-training the employee. Also, the inspector looked at previous NRs and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the HACCP 01 procedure is marked as performed. However, if the inspector finds that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times within the month, he or she may determine that a trend for monitoring noncompliance has developed. In this case he or she will issue an NR and discuss this trend with establishment management during the weekly meeting.

EXAMPLE 2: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. He or she writes an NR for the HACCP 01 procedure. Then he or she performs a HACCP 02 procedure and finds that the product was shipped without a pre-shipment review. In this situation the inspector writes an NR that explains this noncompliance. Next he or she determines whether the

establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, the inspector would take action under the Rules of Practice, 9 CFR part 500.

EXAMPLE 3: While performing the HACCP 01 procedure records review, an inspector observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. The inspector verifies that the corrective actions taken by the establishment meet the requirements of 9 CFR 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.

EXAMPLE 4: While performing the HACCP 02 procedure records review for a single lot of product, an inspector sees in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. The inspector continues to review the records and finds that at pre-shipment review the establishment identified the deviation and took the proper 9 CFR 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation the inspector writes an NR for the monitoring error and determines whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, the inspector should take action in accordance with the Rules of Practice, 9 CFR part 500.

D. How do CSIs document a HACCP noncompliance?

The CSI performs the HACCP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 417.2 – 417.7. The five requirements that the CSI verifies when performing these procedures are **monitoring, verification, corrective actions, recordkeeping, and reassessment**. When the CSI performs one of the HACCP procedures and determines that there is regulatory compliance, he or she documents that the procedure is performed on the procedure schedule. When the CSI determines that the establishment does not meet one of the regulatory requirements, he or she documents the noncompliance on an NR, marking the appropriate trend indicator. The four trend indicators for HACCP are monitoring, corrective action, recordkeeping, and establishment verification. Only one trend indicator should be used for each NR issued.

E. When do CSIs use the monitoring trend indicator?

A CSI should use the monitoring trend indicator when he or she determines that there is noncompliance with the monitoring requirement. This trend indicator should be marked: 1) if the CSI determines the establishment is not monitoring the critical limit at the frequency stated in the HACCP plan; 2) if the CSI determines the establishment is not monitoring the critical limit using the procedures described in the HACCP plan; or 3) if the CSI finds a deviation from the critical limit that the establishment has no way of detecting.

F. When do CSIs use the verification trend indicator?

The CSI should use the establishment verification trend indicator when: 1) the establishment is not conducting the verification activities as described in the HACCP plan, or 2) the establishment is not conducting the verification activities at the frequencies described in the HACCP plan.

G. When do CSIs use the corrective action trend indicator?

The corrective action trend indicator should be used when a deviation or an unforeseen hazard occurs, and the corrective action taken by the establishment does not meet the regulatory requirements. The CSI should use the corrective action trend indicator if the corrective actions taken in response to a deviation from a critical limit did not: 1) appropriately address identifying and eliminating the cause of the deviation; 2) include measures to ensure that the CCP is under control; 3) include measures to prevent the deviation or unforeseen hazard from recurring; or 4) include appropriate disposition of the product.

NOTE: For this trend indicator, the CSI is only to document an establishment's failure to meet the requirements of 9 CFR 417.3. If the establishment finds the deviation or unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

H. When do CSIs use the recordkeeping trend indicator?

The CSI should use the recordkeeping trend indicator when: 1) The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process-monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made; 2) the establishment does not have the decisionmaking documents associated with the selection and development of the CCPs and critical limits, and documents supporting both the monitoring and verification procedures and frequencies; 3) the establishment did not conduct pre-shipment review; or 4) the establishment is not retaining HACCP records for the required length of time.

V. *E. coli* Noncompliance Determination

A. How do the CSIs determine noncompliance?

When the CSI performs the 05A02 procedure (see Chapter III), noncompliance exists if he or she determines:

1. The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.
2. The establishment is not collecting samples at the location in the slaughter process required by the regulations.

3. The establishment is not collecting samples by sponging or excising tissue from the required sites on a livestock carcass, whole-bird rinsing or sponging on the required sites of a turkey carcass or whole-bird rinsing chickens.

4. The establishment is not collecting samples at the required frequency.

5. The establishment is not sampling randomly as per its written procedure.

6. The establishment is not having the samples analyzed at a laboratory using an AOAC Official Method or another method that has been approved and published by a scientific body.

7. The establishment's records of test results do not include at least the most recent thirteen test results.

8. The establishment's records do not express *E. coli* test results in terms of 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; or test results are not expressed in colony forming units per milliliter when the whole bird rinse method is used.

9. The establishment is not retaining records of test results for twelve months.

10. Table 1 in the regulations does not include applicable m/M criteria, and the establishment is not using a statistical process control technique to determine how much variation in test results is within normal limits.

11. Table 1 in the regulations includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria.

B. How will the CSI document findings?

When the CSI makes the determination that one or more of the above requirements are not met, the CSI should document the noncompliance on an NR. The "other" trend indicator is always used with the 05A02 procedure.

VI. Linking NRs

A. When should NRs be linked?

The CSI should only link NRs when the noncompliances are from the same cause. For example:

- If repetitive condensation findings are occurring, the CSI should be linking NRs together to document that there is a trend occurring. This trend may be because the preventive measures are either not implemented or are ineffective in preventing this noncompliance. However, a CSI should use professional judgment in making the determination whether NRs should

be linked. If the establishment has shown a substantial period of compliance, the CSI should not link the NR to previous NRs with the same cause, unless there is a compelling circumstances that justifies doing so, for example, the exact same circumstance that brought about the initial NR has reoccurred.

- An NR under procedure 06D01 for condensation can be linked to an NR written for condensation under procedure 01B02 or 01C02 as the cause is the same. However, an NR written for condensation under 06D01 should not be linked to an NR written for water dripping from the ceiling, from a roof leak, under 06D01. They are both noncompliances and both are water dripping from the ceiling. Both are documented under the same procedure code and the same trend indicators. However, the noncompliance for condensation is from a different cause than the noncompliance for the roof leak.

When the CSI links one NR to another, he or she should reference the previous NR number and date as well as the further planned action that was ineffective in preventing recurrence of the noncompliance. For example:

- The CSI issued NR 25-02 on July 1, 2002, for condensation and the establishment's further planned action was to install fans. On July 8, 2002, the CSI again observes condensation. If the CSI links these NRs, he or she should document in Block 10, that the same or similar noncompliance was documented on July 1, 2002, on NR 25-02. The further planned action of installing fans was ineffective in preventing the condensation noncompliance.

When the CSI starts linking NRs, he or she should be discussing these linkages with plant management during the weekly meetings. The CSI should also include in Block 10 of the NR that these discussions were held.

The purpose of linking NRs is to provide notification to the establishment that the further planned actions are ineffective in, or were not implemented in a way that is, preventing the noncompliance from recurring, and that if the trend continues, the repetitive NR supports an enforcement action under the Rules of Practice.

The CSI should also include a statement in Block 10 of the NR stating that continued failure to meet regulatory requirements can lead to enforcement actions described in 9 CFR 500.4.

The CSI should continue to link NRs together that derive from the same or a related cause until he or she determines that an enforcement action is necessary to bring the establishment into compliance with the regulations. When the determination is made by the CSI that enforcement action is necessary, he or she should contact the DO and to discuss the issuance of an NOIE to the establishment, as described in 9 CFR 500.4. The CSI should always keep his or her supervisor apprised of the situation.

NOTE: It is important to note that noncompliance with SPS requirements can be linked to Sanitation SOP or HACCP noncompliance if the cause of the noncompliance is the same. It is inappropriate for the CSI to have several NRs documenting noncompliance without linkage and then determine there is a trend occurring and list all of the individual NRs to serve as linkage. The NRs should be linked as they are issued, and the concern communicated to the establishment at the weekly meetings.

The CSI should use good judgment in making the determination which NRs to link together. For example:

- If the CSI observes condensation on an overhead that is not contaminating product and makes the determination there is SPS noncompliance, he or she should then determine whether there is a need to link that NR to a previous NR.
- One of the decisions that the CSI needs to make when trying to reach this determination is whether the second noncompliance is an isolated incident or a trend of noncompliance developing. Some of the questions that might assist the CSI to make this decision are:
 1. How much time has lapsed since the previous NR was written?
 2. Was this noncompliance from the same cause as the previous NR?
 3. Were the establishment's further planned actions implemented?
 4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
 5. Is the establishment continuing to implement better further planned actions?
- An establishment might have several hundred pieces of equipment that are cleaned daily prior to operation. The procedures have been implemented as per the Sanitation SOP, the monitoring of the procedures have been conducted, but there may still be a small amount of residue on a contact surface somewhere in the plant at some frequency that was not found during the establishment's monitoring. To determine whether a trend is developing, the CSI would ask:
 1. Are the noncompliances occurring due to the same cause?
 2. Why are the noncompliances occurring? (Negligence, ineffective method, incomplete execution by the plant, or some other reason)

NOTE: The CSI can contact the supervisor for assistance in making this decision. The in-plant inspection team can also contact the TSC for assistance, if needed.

Rules of Practice

PART I -- Enforcement Actions

A. What are the three types of enforcement actions defined in the Agency's Rules of Practice?

9 CFR 500.1 defines three types of enforcement actions. They are :

1. A *“regulatory control action,”* is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;

2. A *“withholding action,”* is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process; and

3. A *“suspension,”* is an interruption in the assignment of program employees to all or part of an establishment.”

B. Although similar, what are the differences between a withholding action and a suspension?

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Both withholding and suspension actions are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, part 1, subpart H.

PART II -- Regulatory Control Action

A. What are the regulatory provisions for a regulatory control action?

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

1. *insanitary conditions or practices;*
2. *product adulteration or misbranding;*
3. *conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or*
4. *inhumane handling or slaughtering of livestock.*

B. What is the purpose of a regulatory control action?

A regulatory control action covers a wide variety of inspection procedures.

A regulatory control action is a limited focus action that is to be used to address specific problems that inspection program personnel come upon in the course of their activities.

A regulatory control action permits inspection program personnel to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility involved until the noncompliance has been corrected. Inspection program personnel are not required to give the establishment prior notification that they are about to execute a regulatory control action.

C. What are some examples of regulatory control actions?

- A regulatory control action may be warranted for direct product contamination with a contaminant that does not result in a food safety hazard.
- A regulatory control action may be warranted with respect to product that is economically adulterated.
- A regulatory control action may also be warranted as a result of regulatory noncompliance even when there is no product contamination or adulteration.
- A regulatory control action should be taken when inspection program personnel are assessing sanitary conditions of the establishment prior to operation and observe product residue from the previous day's production on a contact surface.
- A regulatory control action would be warranted if inspection program personnel determine that packaged product does not meet the net weight requirements.
- Inspection program personnel could initiate a regulatory control action when there is noncompliance with the SPS regulations, if control is needed to prevent contamination of product.

NOTE: Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

D. What procedures are to be used when inspection program personnel take a regulatory control action?

After determining that a regulatory control action needs to be taken, inspection program personnel will notify, as specified in 9 CFR 500.2(b), the establishment orally or in writing of the action and the basis for it. The written notification will be a NR.

As specified in 9 CFR 500.2(c), an establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35. These simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision.

PART III -- Withholding Actions and Suspensions

A. When is prior notification not necessary before taking a withholding or suspension action?

9 CFR 500.3, states that *“FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because*

- 1. The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;*
- 2. the establishment does not have a HACCP plan as specified in 417.2;*
- 3. the establishment does not have Sanitation SOPs as specified in 416.11-416.12;*
- 4. sanitary conditions are such that products in the establishment are or would be rendered adulterated;*
- 5. the establishment violated the terms of a regulatory control action;*
- 6. an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or*
- 7. the establishment did not destroy a condemned meat or poultry carcass, or part or product thereof in accordance with part 314 or part 381, subpart L of this chapter, within three days of notification.*

NOTE: As a suspension only under 9 CFR 500.3(b), the establishment is handling or slaughtering animals inhumanely.

B. Why is prior notification not necessary?

The situations in paragraph III A necessitate prompt action to protect the public health or the safety of FSIS personnel. When this is the case, but only in such cases, a withholding action or suspension action may be taken without prior notification.

Inspection program personnel taking withholding actions without prior notification must be able to document the imminent threat to public health or to the safety of inspection program personnel that made prior notification infeasible.

NOTE: Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

C. When is prior notification necessary before taking a withholding action or a suspension action?

9 CFR 500.4 states that *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:*

- 1. The HACCP system is inadequate under 417.6 of this chapter, due to multiple or recurring noncompliances;*
- 2. The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in 416.13 through 416.16 of this chapter;*
- 3. The establishment has not maintained sanitary conditions as prescribed in sections 416.2 – 416.8 of this chapter due to multiple or recurring noncompliances;*
- 4. The establishment did not collect and analyze samples for E. coli Biotype I, and record results in accordance with 310.25(a) or 381.94(a) of this chapter; or*
- 5. The establishment did not meet the Salmonella performance standard requirements prescribed in 310.25(b) or 381.94(b) of this chapter.*

D. What is the purpose of the prior notification?

The purpose of prior notification, with an opportunity for the establishment to respond, is to provide the establishment with due process procedures.

For paragraph C above, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in

determining how to proceed. The plant also has an opportunity to present corrective actions.

PART IV -- NOIE

A. What is an NOIE?

An NOIE is a notice of intended enforcement action. It provides notification to an establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection as specified in 9 CFR 500.4. The information in the NOIE meets the notification requirements of 9 CFR 500.5 that states: *If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:*

- a. state the effective date of the action(s);*
- b. describe the reasons for the action(s)*
- c. identify the products or processes affected by the action(s)*
- d. provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and*
- e. Advise the establishment that it may appeal the action as provided in section 306.5 and section 381.35 of this chapter.*

A DM issues an NOIE to an establishment for noncompliances that do not pose an imminent threat to public health but that may warrant the withholding of the mark of inspection or suspension of inspection if not corrected. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on discussion with the establishment, the DM may extend the three business days if he or she believes this is necessary.

B. What should a DM do when he or she receives an establishment's response to an NOIE?

The DM should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM determines whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DMs should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM should consider the establishment's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DMs are encouraged to contact staff members from the TSC, the Office of Public Health and Science, and the Office of Policy and

Program Development for assistance in making decisions.

Upon assessing and evaluating the establishment's response, the DM may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM guidance on what procedures to follow:

1. Under what circumstances should a DM accept the establishment's response?

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a description of acceptable corrective and preventive actions from which the DM can find that compliance will be achieved upon implementation, the DM can accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a letter of information to the establishment.

2. Under what circumstances could a DM implement an enforcement action?

If the establishment does not respond or, based on the DM's assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving:

- withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.
- suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.

C. Under what circumstances can a DM defer an enforcement decision?

A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive actions are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to find that the proposed plan, once executed, will prevent recurrence. In this situation, a DM may choose to defer his or her enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM is expected to make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM should not defer a decision for more than 90 days without cause. The DM is to notify the establishment in writing as

to why he or she deferred a decision.

If, at any time, during a period of deferral, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM will immediately notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

PART V -- Abeyance

A. What is an abeyance, and when is it used?

9 CFR 500.5(e) states that *FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.*

B. Under what circumstances could the DM hold a suspension in abeyance?

When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. the establishment presents a plan that demonstrates to the satisfaction of the DM that the establishment has designed corrective and preventive actions that are appropriate to meet the regulatory requirement and ensure that it will not recur; and

2. it is necessary to allow the establishment to operate after implementing these corrective and preventive actions so the DM can determine whether the establishment is able to adequately execute the plan. The DM should not hold a suspension in abeyance until the corrective and preventive actions are implemented, and the abeyance should not be for more than 90 days without cause.

If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

If the DM decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. If this occurs, the DM will instruct the IIC to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM will also contact the Acting Regional Investigation Manager.

PART IV -- VERIFICATION PLANS

A. Verification Plan Design

A verification plan (VP) is to be developed by the EIAO in conjunction with the in-plant inspection team when a decision is made by the District Manager to defer enforcement following the issuance of a NOIE, or a decision is made by the District Manager to hold a suspension in abeyance following the suspension of the assignment of inspection personnel. The VP provides a systematic means for FSIS to verify that an establishment is effectively implementing the corrective measures that were proffered to FSIS. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO is to work with the in-plant inspection team, including the Frontline Supervisor, in the development of the VP. The VP should be referenced in the deferral or abeyance letter issued to the establishment.

The VP is to:

1. describe the verification activities that will be performed by inspection personnel based on the establishment's corrective measures.
2. list the ISP procedure code associated with each verification activity that will be carried out by the inspection team.
3. list the regulatory cite associated with each verification activity.
4. be developed so that the verification activities identified in the VP are performed as part of scheduled PBIS procedures.

B. Verification of Establishment's Corrective Measures

1. On a weekly basis the in-plant team is to report via e-mail to the District Office the results of the activities conducted under the VP.
2. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings. The in-plant team may request that the EIAO conduct a follow-up visit to an establishment that has had an enforcement action deferred or is under a suspension action that is held in abeyance to determine the overall effectiveness of the establishment's corrective measures.

3. Also, the in-plant team may request a visit at the end of the deferral or abeyance period to determine whether the action should be closed. This is in addition to the daily verification activities done by the in-plant team using the VP.

Direct questions regarding this directive to the Technical Service Center at (800) 233-3935.




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