
Documentation

Completing the Noncompliance Record (NR), FSIS Form 5400-4

The Performance Based Inspection System (PBIS) Application 5.1.3., automatically generates a NR, when the CSI enters a noncompliance result code for the procedure on the Procedure Results screen. NRs are the forms completed by inspection program personnel and issued to the establishment when there is a failure to comply with regulatory requirements.

Type of noncompliance

Food Safety

Any 01 – SSOP

Any 03 - HACCP

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 Requirements

06D01 - SPS

How to complete the sections/blocks of the NR

1. **Date** - Automatically entered when the date is selected on the procedure results screen of PBIS 5.1.3.
 2. **Record No.** - Automatically entered by PBIS 5.1.3 sequentially by year (i.e., 1-04, 2-04, 3-04, etc.) regardless of who completes the NR.
 3. **Est. No.** - Automatically entered when the establishment is selected on the procedure results screen of PBIS 5.1.3.
 4. **To (Name and Title)** - Automatically entered as a result of selecting the name and title of the responsible establishment official from the list of “points of contact” in the **Report to** and **Title** fields of the NR section on the procedure results screen of PBIS 5.1.3. For a HACCP system noncompliance, the name of the person who signed the HACCP plan should be selected. For a Sanitation SOP regulation noncompliance, the name of the person who signed the Sanitation SOPs should be selected. For SPS noncompliance, the CSI should enter the name of the establishment official responsible for responding to the NRs. The name and title of the responsible establishment official may be manually entered if it does not appear in the drop-down list.
 5. **Personnel Notified** - Automatically entered as a result of selecting or manually
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entering the name of the person notified on the NR section in the procedure results screen of PBIS 5.1.3. The name(s) of the establishment management personnel who was/were notified about the noncompliance may also be manually entered on the NR.

6. **Relevant Regulations** - Automatically entered as a result of selecting the applicable regulations from the “**Relevant Reg(s)**” pick list on the NR section accessed from the procedure results screen of PBIS 5.1.3. A short description appears next to each regulation to assist the inspection program employee in selecting applicable regulations. A new regulation look-up feature is also available to allow the inspection program employee to view particular sections of the regulations. All of the regulations the plant fails to meet as determined by the inspection program employee while performing an inspection procedure should be entered in this section/block. For example, if the plant failed to keep the processing room floor in good repair and did not provide ventilation adequate to prevent condensation from creating an insanitary condition, the inspection program employee would click on the box next to SPS regulation subpart 416.2(b)(1) and 416.2(d).
7. **Relevant Section/Page of Establishment Procedure/Plan** - Manually 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. The written generic *E. coli* specimen collection procedure is considered “other.” When the noncompliance is not related to a procedure or plan leave this section blank.
8. **ISP Code** - Automatically entered as a result of entering a noncompliance result code for the procedure in the procedure results screen of PBIS 5.1.3.
9. **Noncompliance Classification Indicators** - Automatically entered as a result of entering the result code for the noncompliance classification indicator in the procedure results screen of PBIS 5.1.3. Inspection program personnel need to select the result code for the classification trend indicator that best describes the noncompliance. 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, the time it occurred and 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 and how much product was contaminated, and the action taken.

- Explain that the establishment management has received adequate oral and written notification.
- Include the plant's response to any previous notification and any corrective actions that were unsuccessful when the noncompliance represents a developing trend in noncompliance.

The CSI should link the current NR to the previous NR by listing the previous NR with a 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.

- Include any applicable deadlines.
- Reflect the use of regulatory control actions (tags).
- Keep typing if more space is needed to describe the noncompliance.

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 plant management when management elects not to respond in writing.

Note: The CSI should not identify what immediate and further planned actions to take or require the plant to take any particular immediate and further planned actions. This is the plant management's responsibility!

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 signs after inspection program personnel have verified the establishment has brought itself into compliance with the regulatory requirement that resulted in the issuance of

the NR and, if necessary, the NR Continuation Sheet.

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.
