Document a Noncompliance Record Job Aid

Instructions: Review this Job Aid and policy documents, regulations, and inspection methodologies with a mentor.

Acronyms/Definitions

- PHIS – Public Health Information System
- Noncompliance – A finding by IPP that an establishment has not complied with one or more regulatory requirements.
- Noncompliance Record (NR) – PHIS generates an NR for noncompliance documented under a verification task. Each NR may contain one or more noncompliances.
- FSIS Form 5400-4 – The Noncompliance Record form number.

Procedure Overview

- When IPP find noncompliance with one or more regulations, they document the noncompliance in PHIS.
- Noncompliances are to include a description of how IPP's findings support the determination that the establishment did not meet regulatory requirements.
- IPP are to associate two or more NRs when the NRs indicate an ongoing trend of related noncompliances.
- IPP are to document how the noncompliance is related to previous NRs or other findings within the establishment in the Inspection Notes feature of PHIS.

Basic Procedure

- Gather, assess, and determine (FSIS Directive 5000.1, Ch. I., Sec. VII.):
    - Gather information (e.g., observe establishment employees).
    - Assess the significance of observations and information in the context of the establishment's operations, products, and food safety system.
    - Determine if there is regulatory noncompliance.
- Identify noncompliance with one or more regulations.
- Take a regulatory control action, when necessary and per 9 CFR 500.2.
- Notify establishment management as soon as possible of the noncompliance, prior to documenting in PHIS.
- Document the noncompliance in PHIS under the inspection task (FSIS Directive 5000.1, Ch. V, Sec. I. & II.).
    - PHIS automatically enters the date, NR number, inspection task, and establishment number.
    - IPP:
        - Select one or more regulatory citations.
        - Document a description of noncompliance.
        - Record affected product (weight and product name, lot number).
        - Check appropriate box if product was adulterated/misbranded.
        - Enter the US Retained/Rejected tag(s) number(s).
        - Include sample form number if NR is associated with FSIS sample result.

        - Select the name of the establishment official to whom the NR is addressed to.
        - Enter the names of establishment management who were notified.
- Review the NR to verify the description of the noncompliance includes:
    - **While** – while performing what inspection task?
    - **When** – when was the noncompliance discovered (time and date)?
    - **What** – what is the noncompliance? What were the exact conditions? What is the scope of product or equipment affected (if applicable)? What action did the establishment take or propose?
    - **Where** – where, specifically, in the establishment (location)?
    - **Who** – who in establishment management did IPP notify?
    - **Why** – why is there noncompliance? **How** do IPP's findings support the determination that the establishment did not meet regulatory requirements? Why did IPP assess that this specific finding is noncompliant (rather than compliant) with the regulations specified?

  Note: Most Sanitation SOP and HACCP noncompliances are related to the establishment's written programs. A clear description of how IPP determine their observations support a determination of noncompliance in the description of the NR will often involve some reference to one or more portions of the establishment's written programs. A direct quote is not necessary but if the observation is a noncompliance because establishment has not implemented the program as written, the description needs to explain that.
- Determine if the NR is associated with previous NRs (FSIS Directive 5000.1, Ch. V, Sec. VII.).
    - If applicable, associate the NR with the most recent NR in the ongoing trend.
    - In the NR description, include:
        - The number of the associated NR and a description of how IPP determined the noncompliance represents a trend.
        - A description of unsuccessful further planned actions taken by the establishment.
    - **Note:** IPP discuss developing trends of noncompliance with establishment management at the weekly meeting. IPP also notify their supervisor of trends.
- Review the NR to verify it is accurate, clear, and concise.
    - Remove unnecessary words.
    - Verify use of active language.
    - Proofread for spelling and grammar errors, appropriate case (i.e., capitals/lowercase).
    - Verify the NR supports how the establishment did not meet regulatory requirements.
    - Avoid statements of opinion or speculation.
    - Verify the narrative is easily understood by people unfamiliar with the establishment.
- "Finalize" the noncompliance in PHIS (FSIS Directive 13000.1, Sec. IV., 9. & 10.).
- Print, sign, and present the noncompliance to establishment management as soon as practical.

- Verify the establishment takes necessary actions to return to compliance.
    - When regulations require specific corrective actions, verify that the establishment meets those regulatory requirements (9 CFR 417.3, 416.15).
- Mark the NR and associated inspection task "completed" when the establishment has returned to compliance with all regulations found noncompliant in the NR.

Discussion Points

- Discuss how IPP document a supportable NR: plan, organize, write, and edit.
- Discuss practical writing skills IPP use to document clear, concise NRs.
    - Spelling (their/there, form/from, preformed/performed, too/to/two)
    - Wordiness ("Each and every carcass" vs "Each carcass")
    - Passive vs. active voice ("The CCP was not monitored by the establishment" vs. "The establishment did not monitor the CCP")
    - Sequence of events
    - Proofread
- Discuss how in situations where the establishment identifies the failure, performs corrective actions, and returns to compliance, there is no noncompliance.
- Discuss what IPP do in PHIS if the establishment appeals an NR (FSIS Directive 13000.3, Sec. IV. & V.).

Knowledge Check

- Describe what IPP are to include in the description of a noncompliance.

Resources

- FSIS Directive 5000.1 – *Verifying an Establishment's Food Safety System*
- FSIS Directive 13000.1 – *Scheduling In-Plant Inspection Tasks in PHIS*
- FSIS Directive 13000.3 – *Responding in PHIS to Industry Appeal of an NR*
- AgLearn: Master NR Writing
- IM Workbook – Noncompliance