PHIS INSPECTION VERIFICATION (PART 2)

Objectives

After completing this section of the training, participants will be able to:

1. Define the term "noncompliance".

2. Document noncompliance on a Noncompliance Record (NR) in PHIS

3. Identify the information that must be recorded on the NR when IPP are documenting a trend in noncompliance.

4. Identify the activity IPP must perform before an NR can be completed.

Documenting Noncompliance in PHIS

Noncompliance is defined as an establishment's failure to meet a regulatory requirement. When IPP find regulatory noncompliance, they are to:

1. Notify a representative of establishment management as soon as possible either verbally or in writing,

2. Document the noncompliance on a Noncompliance Record (NR, FSIS Form 5400-4) in PHIS and present the noncompliance to establishment management,

3. Verify that the establishment takes necessary actions to bring itself into compliance with the applicable regulation, and

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   Note: PHIS will not allow the inspection task to be designated as "completed" until IPP have verified and documented that the establishment has brought itself into compliance with the regulatory requirements that were not met and resulted in the issuance of the NR.
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IPP should not allow the establishment to address noncompliance without documenting it (there are few exceptions identified the HACCP regulatory process module). To complete the NR, IPP follow the instructions in Chapter V of FSIS PHIS Directive 5000.1 and the PHIS user guide on the insideFSIS intranet PHIS page.

The NR serves as FSIS's official notification and documentation of the establishment's failure to meet one or more regulatory requirements. NRs are legal documents. They are the basis for supporting further enforcement actions that the Agency *may* take against an establishment. NRs are also the building blocks for a legal case that may be developed against an establishment. If an FSIS administrative enforcement action has been taken and appealed by an establishment, an administrative law judge, who will make a decision concerning the case, will review all the evidence supporting the enforcement action. In many of these cases, the NR generated by IPP may be the only evidence provided to the judge that supports FSIS's actions. The NRs provided to the judge in those cases must speak for themselves. Therefore, it is extremely important that IPP use good documentation practices and follow Agency policy when completing NRs. For instance, IPP must ensure that the written description of noncompliance documented on an NR adequately supports the determination of regulatory noncompliance and the NR is accurately completed. IPP **must** provide establishment management with a copy of the NR. By notifying the establishment of noncompliance with the regulatory requirements both orally and in writing via the NR, IPP are providing the establishment with due process.

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Note: Supervisory personnel are to support IPP in documenting noncompliances when they occur.
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Only *one NR* is completed per inspection task when noncompliance is found. However, *more than one noncompliance* can be documented on the NR.

In some establishments, inspection tasks may take all day, more than a day, or a week or several weeks for the IPP to complete. For these inspection tasks, PHIS enables IPP to document noncompliance on the NR when it is found and provide a copy of the NR to establishment management *before* the inspection task is completed. For example, a particular inspection task takes three days to complete in the establishment. On the first day of performing the task, the IPP finds noncompliance with a regulatory requirement. IPP must finalize each individual noncompliance and present it to establishment management as soon as practical. Therefore, she notifies the establishment orally and presents the noncompliance to the establishment by giving management a copy of the NR at the end of the workday. On the third day of performing the task, she finds noncompliance with a different regulatory requirement, notifies the establishment orally, and presents this noncompliance to establishment on **another copy** of the NR with the same number. In this example, there is one NR with multiple pages. Each page of the NR documents a different noncompliance and cites a different regulation but the number is the same on each page.

Noncompliances and NRs have a status displayed in PHIS. The noncompliance and NR statuses are defined in the following table.

	Status in PHIS	**Definition**
Noncompliance (NC)	Open	• A noncompliance has been documented in PHIS
	Finalized	• The noncompliance is ready to deliver to establishment management
Noncompliance Record (NR)	Open	• An NR has been created in PHIS
	Completed	• *All* of the mandatory regulations have been verified • The establishment has brought itself into compliance with the regulations for each noncompliance in the NR.

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Note: IPP can issue a printed copy of the NR to establishment management at any time after it is created, e.g., when the first noncompliance is documented and finalized, when another noncompliance is documented and finalized on the existing (open) NR, or after the NR is completed.

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

When IPP determine that the establishment has not met one or more regulatory requirements, they check the "**Regulatory Noncompliance**" box at the bottom of the "Regulations tab" of the Inspection Results page, and then click "Save" in PHIS. Checking the "Regulatory Noncompliance" box enables the Create/Edit NR button on the bottom of the Inspection Results page. Much of the information that appears in the sections/blocks on the printed NR is automatically added by PHIS. Some blocks on the printed NR are completed with information entered by the IPP. For instance, the IPP must provide a complete, clear, and concise description of each noncompliance.

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Note: If PHIS is not operational, IPP may complete and issue a paper copy of the NR (FSIS Form 5400-5). However, once PHIS becomes operational again, IPP are to record the applicable procedure and results and document the NR in PHIS.

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Sections/Blocks of the NR

At the top of the NR, PHIS automatically checks a box to indicate the noncompliance relates to "Food Safety" or "Other Consumer Protection" based on the inspection task name.

1. **Date**—Automatically generated by PHIS from the Inspection Results page.

2. **NR number**.—Automatically generated by PHIS. The number of the NR is a random, system generated number. It contains 14 alpha numeric characters, but does not have any information like establishment number or date associated with it. The number ends with a letter N and it is usually followed with a /1. If additional noncompliance(s) is later recorded for the same task, there may be additional NR pages identifying those noncompliances. Those pages will have the same NR number but it will be followed with a /2, 3, and so on. Having PHIS randomly generate the number for the NR prevents the duplication NR numbers.

3. **Est. No.—**Automatically generated by PHIS from the Inspection Results page. The establishment number is associated with the task on the task calendar.

4. **To (Name and Title)**—PHIS will provide a pick-list of names from the PHIS Establishment profile "Contacts" page to select from or the IPP can manually enter (type) the name and title of the **responsible person**. 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 SOP should be selected. For SPS noncompliance, IPP should enter the name of the establishment official responsible for responding to the NRs. PHIS adds the name of the individual the IPP selected to this block of the NR.

5. **Personnel Notified**—IPP enter the names of the establishment management personnel who were notified about the noncompliance. PHIS will provide a pick-list of names from the PHIS Establishment profile "Contacts" page. IPP select one or more names from the list offered in PHIS. If IPP notified someone other than one of the listed contacts, they manually enter (type) the name and title of the establishment management personnel in the other personnel notified fields on the Noncompliance page. PHIS will add the name(s) of the individual(s) the IPP selected to this block of the NR.

6. **Relevant Regulations**—IPP check one or more the regulatory citations appearing in the pick-list on the **Noncompliance page** in PHIS. PHIS will provide a regulatory citation pick-list based on the regulations that were checked as verified by the IPP on the Inspection Results page. IPP verify that the regulatory citation pick-list includes all the specific regulations not met. If a particular regulation is not available in the PHIS list of regulations on the

Inspection Results page, they should type it in the noncompliance description text block of the NR. PHIS will add the regulations that the IPP checked as non-compliant to this block of the NR.

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Note: PHIS tracks and counts each regulation verified and each regulation that is noncompliant. An establishment's performance is based on the individual instances of regulatory noncompliance entered into PHIS and not on the number of NRs issued.
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6a. **Associated NR(s)**—IPP associate NRs when a developing trend in noncompliance is occurring within the establishment . IPP should only associate NRs together when the noncompliances are from the **same cause.** PHIS will allow IPP to review recent NRs with similar documented noncompliances and select one or more NRs to be associated to the new NR. PHIS will add the associated NR numbers to block 6a.

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Note: Associating NRs will be discussed in detail later in this module and demonstrated in the hands-on learning portion of this module.
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7. **Titles of HACCP or SSOP Plan or other supporting Documentation**—For HACCP verification tasks, IPP select the HACCP plan under the Activity Tab of the Inspection Results page that was verified during the performance of the HACCP task. PHIS will provide a pick-list of the names of the HACCP plans from the Establishment profile "HACCP" page. The IPP may also manually enter (type) the name of another HACCP plan if it is also verified. The HACCP plan name is added to this block by PHIS.

7a. **Name of CCP(s) or Prerequisite Program**—For HACCP verification tasks, IPP manually enter (type) the name of CCP(s) that was verified during the performance of the HACCP task in the box under the Activity Tab of the Inspection Results page. They also select prerequisite program (if applicable) that was verified during the performance of the HACCP task under the Activity Tab of the Inspection Results page. PHIS will provide a pick-list of the names of the prerequisite programs from the Establishment profile "HACCP" page. The IPP may also manually enter (type) the name of another prerequisite program if it is also verified. PHIS will add the CCP(s) and/or prerequisite programs recorded in the Inspection Results page to the NR.

Note: Performing the HACCP verification tasks is discussed in detail later in this course.

8. **Inspection Task**—Automatically generated by PHIS from the Inspection

Results page. The task may be a routine or directed task.

9. **Verification Activity**—Automatically generated by PHIS from the Inspection Results page. When IPP claim (start) the task, they are required to select the verification component (review & observation or recordkeeping or both) used to verify compliance with the regulations.

9a. **Affected Product Information**—IPP check the product adulteration box on the Noncompliance page to indicate that the documented noncompliance resulted in adulterated or misbranded product being produced. Finding fecal material while performing the Livestock Zero Tolerance task would be an example of when the product adulteration box should be checked. If the adulteration box is checked, IPP enter (type) **the product name, lot number, approximate weight** and any other information available in the data fields on the Noncompliance page to identify the specific amount of product affected by the noncompliance. PHIS will automatically add the product information on the Noncompliance page to this block of the NR. When direct contamination or adulteration is not observed during the task, IPP leave the data fields on the Noncompliance page blank.

9b. **Retain/Reject Tags**—When IPP take a regulatory control action based on the noncompliance finding, e.g., retain contaminated or adulterated product or reject equipment or facilities, they manually enter (type) the number of the tag(s) in the appropriate field on the Noncompliance page. PHIS will automatically add the tag number(s) for the Noncompliance page to this block.

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Note: If a regulatory control action was taken, IPP are to immediately notify establishment management orally or in writing and provide the basis for taking the regulatory control action.
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10. **Description of Noncompliance**—IPP include the following elements in their description of the noncompliance in the text box of the Noncompliance page:

- A clear, concise, and complete description of each noncompliance including the exact problem, the time it occurred and its location, and the effect on product, if any. The description should clearly explain how the IPP findings support the determination that the establishment did not meet regulatory requirements.

- An explanation of how the IPP notified establishment management of the noncompliance.

- Reflect the use of a regulatory control action (include the tag number) or a

withholding action.

- If there is a developing trend of noncompliance, IPP add additional information to the description of the noncompliance. IPP also associate the current NR to the previous NR that documents the noncompliance from the same cause. IPP include:

  ➢ A description of how the IPP determined that this noncompliance is from the same cause as the previous noncompliance, and

  ➢ The previous NR number and establishment's immediate and further planned actions or corrective actions and preventive measures taken for the previous noncompliance that were unsuccessful in achieving compliance.

If another noncompliance is found during the remainder of the inspection task, IPP can document it separately in PHIS. PHIS will add the description of the noncompliance from the Noncompliance page to this block.

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Note: In most cases, it is not necessary to include references to the Acts or a complete quote of the applicable regulation.
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The following examples demonstrate documenting noncompliance in the text box on the Noncompliance page in PHIS. Refer to Attachment 1 of this handout.

Noncompliance Description Example 1: *At approximately 0410 hours, on 1/27/2016, after the establishment's pre-operational inspection and before the start of production, I performed the Pre-Op SSOP review and observation task. I observed the following noncompliances: Rust on the auger and auger throat of the #2 grinder; rust on the auger and blender arms of the small Hobart grinder; rust on the crossbar on top of the hopper to the stuffer; and dried residue on the blade guides and the bottom of the pulley on both band saws. I applied U.S. "Rejected" tags (#B67587521 through 6) to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws. I verbally informed the sanitation foreman of the noncompliance with 416.13(a). He immediately had the equipment appropriately cleaned to restore sanitary conditions.*

Noncompliance Description Example 2: *At approximately 1425 hours, on 1/28/2016, while performing the SPS task, I observed condensation dripping from pipes attached to the ceiling onto chicken parts on belt #1 in the boning room. Belt #1 was U.S. "Rejected" with tag B2746867. Approximately 150 lb of product with lot #1282012Z was U.S. "Retained" with tag B2746868. Ms. Mary White was verbally notified of the direct contamination of product and*

the insanitary condition of belt #1. She was informed that the regulatory control actions would remain in effect until the establishment meets the requirements of 9 CFR 416.15.

11. **Signature of Inspection Program Employee**—When IPP are satisfied with the description of the noncompliance in the text box on the Noncompliance page, they check the "Finalized" box at the bottom of the page, print and sign the copy of the NR given to the establishment.

12. **Plant Management Response**—The establishment **is not** required to provide a response for the noncompliance documented on the NR. Providing a response to the NR is **voluntary** on the part of the establishment. However, the establishment is responsible for bringing itself back into compliance with the regulatory requirements. When the establishment elects to respond to the noncompliance, it may provide "immediate action" and "further planned action". "Immediate action" represents the action the establishment takes to correct the noncompliance, including appropriate product disposition. The "further planned action" is the action to prevent recurrence of the noncompliance. The establishment may respond to the noncompliance in a number of ways.

- When the establishment has e-authentication, it may respond to the NR electronically in PHIS. To observe the establishment's response, IPP click the "Response" tab on the Noncompliance Record page.

- If the establishment response to the NR is provided in writing through electronic means (PDF file or word file) to the IPP, he or she can upload the file to the Response tab on the Noncompliance page.

- The establishment may provide immediate and further planned actions on the printed copy of the NR and return it to the IPP.

- The establishment may provide a verbal response to the NR (e.g., verbally provide immediate and further planned action or corrective action and preventive measures). IPP **may** record that response on the **printed copy of the NR**. However, there is no requirement for IPP to record management's verbal response on the NR. If IPP elect to document the establishment's response on the printed copy of the NR, they can add **brief synopses** of the verbal response in block 12. They should not transcribe all the information verbatim. Entering the establishment's response to correct the noncompliance may assist FSIS in the future especially if the action does not prevent recurrence of the noncompliance.

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  Note: The preferred method of documenting the establishment's verbal responses to noncompliance documented on NRs is in weekly meeting

notes and subsequent MOI. **IPP *do not* enter the establishment's verbal response to the NR or the written response on the printed NR in the *Response tab* of the Noncompliance Record page of PHIS.**
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IPP should not tell the establishment what immediate and further planned actions to take to correct and prevent a noncompliance *or* require the establishment to take any particular immediate and further planned actions to correct and prevent a noncompliance. Determining the proper action to take is the establishment management's responsibility!

13 and 14. **Signature of Plant Management and Date**—If establishment management responds in writing in block 12 of the copy of the NR given to them, an establishment official should sign and date the printed copy of the NR.

15 and 16. **Verification Signature of Inspection Program Employee and Date**— Once an establishment is back in compliance with all the regulatory requirements documented on the NR as noncompliant, IPP check the "NR Completed" box on the bottom of the Noncompliance Record page in PHIS. The IPP also signs and dates the printed copy NR in the government file after verifying the establishment has brought itself into compliance with all the regulatory requirements that resulted in the issuance of the NR as described in the next section.

Maintaining Copies of NRs in the Government Office

IPP maintain an NR file that is divided into two sections in the government office at official establishments. One section of the NR file is identified as "open". The other section is identified as "completed".

The Open NR File

In addition to giving the establishment a copy of the printed NR, the IPP places a copy of the NR in the "open" file when the IPP has not verified that the establishment is back in compliance or the establishment **has not** brought itself into compliance with the regulatory requirement that resulted in the issuance of the NR. Depending on the noncompliance, the establishment may be allowed a period of time to bring itself into compliance with the regulations provided operations would not result in the preparation of adulterated product.

Remember that the establishment **is not** required to provide immediate and further planned actions in writing on the NR. However, if the establishment returns a copy of the NR to the IPP with proposed immediate and further planned actions in block 12, the IPP removes the NR without the establishment's

response from "open file" and replaces it with the NR that has the establishment's response. The NR without the establishment's response served as a place holder to indicate that an NR had been issued until the establishment returned a copy of the NR with its response. If the establishment proposed immediate and further planned actions orally, the IPP may document a summary of the establishment's oral response on the NR and place it in the "open" file. The NR remains in the open file in the government office and the electronic version of the NR in PHIS remains "open" until the establishment has brought itself into compliance with the regulatory requirements.

The Completed NR File

When the IPP verifies that the establishment has brought itself into compliance with the regulatory requirement(s) that resulted in the issuance of the NR, the IPP removes the NR from the "open file" completes block 15 and 16 of the NR (signs and dates) and places the NR in the "completed" file. If the establishment provided a response in writing on the NR or the IPP documented the establishment's oral response on the NR, the IPP signs and dates the copy of the NR with establishment's documented written or oral response. The IPP also checks the "NR Completed" box on the Noncompliance Record page in PHIS. IPP **do not** sign the copy the NR in the open file in the government office until they have verified that the establishment has brought itself into compliance with the regulations.

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Note: In some noncompliance situations, the establishment may have taken immediate action and the IPP verified that the establishment had brought itself into compliance with the regulatory requirement(s) before the IPP gave the NR to the establishment, e.g., pre-op sanitation noncompliance. In this case, the IPP completes blocks 15 and 16 of the NR (signs and dates) and places the NR in the "completed" file.
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Completing "Open" NRs

IPP review the "open" NR file in the government office or the "open" NRs in PHIS by clicking the arrow next to Inspection Verification in the left navigation menu and then clicking the Noncompliance Records link daily. During the performance of inspection tasks, they are to verify that the establishment has brought itself into compliance with regulatory requirements that were not met and resulted in the issuance of an NR.

Verifying that the Establishment is Back in Compliance Example 1: Upon arriving at the establishment on Monday, a relief IPP reviews the open NR file in the government office and sees that the assigned IPP had issued an NR last Tuesday for a 1 foot by 8 inch hole in the processing room floor, under the product belt conveyor of line one, that had an accumulation of product residue

from previous days' production. The establishment stated in block 12 of the NR that the floor would be repaired over the weekend. While performing the Pre-Op SSOP Review and Observation task in the processing room, the relief IPP examines the floor under the product belt conveyor of line one and sees that the floor has been repaired and there is no longer an insanitary condition.

Upon returning to the inspection office, the relief IPP removes the NR from the "open" file, signs and dates blocks 15 and 16 because the establishment has brought itself into compliance, and then transfers it to the "completed" NR file. When he logs into PHIS, he accesses the NR in PHIS and checks the "NR Completed" box on the Noncompliance Record page.

The relief IPP wants to make sure that the regularly assigned IPP is aware of this action. He creates an Inspection Note, provides information about his observations, and points out the completed NR.

If the noncompliance necessitates the establishment to take corrective action required by 9 CFR 416.15 or 417.3, the NR can only be completed after the IPP has verified that the establishment has met the requirements of 9 CFR 416.15 or 417.3. Establishments are not required to indicate corrective and preventive measures on the NR. Hence, IPP may need to verify corrective actions by reviewing establishment records.

Verifying that the Establishment is Back in Compliance Example 2: *On Monday, the assigned IPP found a deviation from a critical limit while performing the HACCP verification task and notified the establishment. The establishment is required to take the corrective actions in 9 CFR 417.3(a) when there is deviation, and the IPP is required to verify that the establishment's corrective actions meet the regulatory requirements in 9 CFR 417.3(a).*

The IPP observes the establishment segregate and hold the affected product, identify and eliminate the cause of the deviation, and record these actions on the corrective action log. The establishment also makes entries on the log that states "we will monitor the critical limit hourly instead of twice per shift as written in the HACCP plan for the next two days to ensure that the CCP is under control and meet with the maintenance supervisor to establish a preventive measure". She documents the noncompliance in the PHIS and gives the establishment a copy of the NR. The establishment returns the NR to the IPP with the following notation in block 12 "see corrective action log". She places the NR in the "open" file.

On Thursday, she reviews the establishment's corrective action log and monitoring records for the specific production involved in the deviation to finish the HACCP verification task. She finds that the establishment has established a standard operating procedure (SOP) as a preventive measure and the additional monitoring checks were performed and no additional deviations were found. The corrective action log indicates that the affected product is still on hold pending a review of the deviation by a processing authority. On Friday, the establishment

tells the IPP that the affected product will be destroyed. The IPP oversees the destruction of the affected product and reviews the corrective action log, which has the product disposition entry.

Upon returning to the inspection office, she removes the NR from the "open" file, signs and dates blocks 15 and 16 because the establishment has brought itself into compliance, and then transfers it to the "completed" NR file. She already verified all of the other mandatory regulations for the task so when she logs into PHIS, she also accesses the NR in PHIS and checks the "NR Completed" box on the Noncompliance Record page. Then, she checks the "Inspection Completed" box on the Inspection Results page.

Hands-on Activity

The following hands-on activity is intended to provide familiarity and experience with the PHIS **Inspection Results** and **Noncompliance** pages that are used to document the results of inspection tasks performed by IPP. For this hands-on activity, you (as Robert Barclay) will document the results, including noncompliance, for a Pre-Op SSOP Review and Observation task.

Follow these steps along with the instructor.

- ‣ Open the laptop
- ‣ Log-onto laptop:
  - ▪ User Name: *FSIS_user*
  - ▪ Password: *FSIS*
- ‣ Double click the Start Internet Explorer icon
- ‣ PHIS Log-in
  - ▪ Select User: **Robert Barclay (your #)**

Schedule a Pre-Op SSOP Review and Observation Task

1. Click **Task Calendar** option in the left navigation menu
2. From the **Establishment Task List,** click the drop-down arrow and select **Holland Point Foods** as the establishment
3. Type **SSOP** in the task name filter

   Note: Entering a word like "Livestock", "SSOP" or "HACCP" typed into the filter is enough to narrow the establishment task list.

4. Click the **Filter icon**
5. Click **Contains** in the pick list
6. Find the **Pre-Op SSOP Review and Observation task** on the task list
7. Click the **Add** link in the routine column for the **Pre-Op SSOP Review and Observation task**

8. Type the number **"1"** in the box for **Today's Date** in the task calendar pop-up window
9. Click the **Save** button
10. Scroll down to the **Task Calendar** and see if the **Pre-Op SSOP Review and Observation task** is on the calendar for **Today**

Enter the Inspection Result for the Pre-Op SSOP Review and Observation Task

Before the results from performing an inspection task can be entered on the Inspection Result page, the IPP must claim the task. The IPP that claims the task is responsible for performing it and documenting the results. Recall from the task calendar presentation, that another IPP can complete it, but he or she will have to unlock the task and provide a reason for unlocking it.

1. Right click on the Pre-Op SSOP Review and Observation task and select **Document**
   - Right clicking on the task displays the **Task Menu**
   - The **Inspection Results** page is displayed when **Document** is selected from the Task menu
2. Click the **Activity** tab
3. Click the **Square** in upper right corner of the pop box to maximize the screen
4. Click the radio button in front of **Both** for the verification component
5. Click the **Save** button
   - The task is now claimed
   - A message at the top of the screen says "inspection result saved successfully**"**

   Note: If a verification component is not selected before the IPP saves, he or she will get an error message at the top of the page.

IPP can add additional information directly related to performing the task in the comments or affirmative findings texts boxes under the Findings tab.

6. Click the **Findings** Tab
7. In the **Comments** box **type**: "The RTE product room and blending area were inspected because establishment SSOP records indicated product residue on food contact surfaces was found twice last week"

IPP identify the specific regulations they verified during the performance of each inspection task. PHIS does not allow a task to be designated as "completed" in the system unless all of the mandatory regulations for the task have been verified or the N/A (not applicable) box has been checked and a justification for not verifying the regulation has been provided.

8. Click the **Regulations** tab
9. Check the **mandatory regulations** as verified- 416.13(a), 416.13(c), 416.14, and 416.16(a)

When IPP find that the establishment did not comply with a regulatory requirement, they must document the noncompliance on an NR. To document the noncompliance, IPP **must enable the Create/Edit NR button** in the Inspection Results page footer.

10. Check the **Regulatory Non-compliance** box

   Note: Checking the Regulatory Noncompliance box is the only way to create a NR in PHIS.

11. Click the **Save** button
   - The Create/Edit NR button is now enabled
12. Click the **Create/Edit NR** button
   - The Noncompliance Page in PHIS is presented
13. Review the **Noncompliance Record** page

The Noncompliance page in PHIS has three tabs: General, Noncompliances, and Response. The "General" tab is the default view for the Noncompliance Page.

14. Review the information on the **General** tab

Information found on the General tab includes the date, NR number, and the status of the inspection task. The IPP may also associate a Memorandum of Interview (MOI) and Food Safety Assessment (FSA) with this noncompliance. We will demonstrate associating an MOI with an NR in another hands-on exercise.

15. Click on the **Noncompliances** tab
   - A blank noncompliance grid is displayed
16. Click **Add Noncompliance**
17. Slowly scroll down and **Review** the information on the **Noncompliance page**

At the top of the "Noncompliance" page are the regulations that the IPP verified during the performance of the task. These were selected (checked) from the "Regulations" tab on the Inspection Task Results page. In the middle of the page is the text box for entering the description of the noncompliance. Under the noncompliance description text box there are additional product information text boxes including entering Regulatory Control Action tag numbers. At the bottom of the page, IPP select the name of establishment individual that the noncompliance and associated NR is addressed to which is usually a pre-determine contact individual. They also identify the name of the individual(s) that

were notified of the noncompliance. These names should have been entered on the establishment profile. IPP may add additional names that are not on the pick-list by typing in their first and last names and clicking the "Add" button. The NR addressee name is mandatory. If this individual is not selected, the IPP will get an error message.

18. Scroll to the top of the page, document the noncompliance and complete a draft of the NR (FSIS Form 5400-4)
19. Check **416.13(a)** as the noncompliant regulation

The noncompliance description needs to a clear, concise, and complete. It needs to include the exact problem, the time it occurred and its location, and the effect on product, if any. The description should clearly explain how the IPP findings support the determination that the establishment did not meet regulatory requirements.

20. Type the **Description:** While performing Pre-Op Sanitation inspection on 2-2-2016 at 6:44 am after the facilities were released for inspection, I observed meat and fat scraps from the previous day's production on meat slicer #5 and the mixing blades of the vacuum blender. I applied U.S. Rejected tag B00001 to the slicer and U.S. Rejected tag B000002 to the blender. I verbally informed Diana Popadoupolis of the noncompliance with 416.13(a). She immediately had the equipment cleaned to restore sanitary conditions. The sanitation record was not available when this task was performed.

21. Type **Tag #s B000001 and B000002** in the box
22. Click the Addressed to down arrow and select: **Mike Adams**
23. Select Personnel Notified: **Diana Popadoupolis**
24. Notice the **NC Finalized** box but don't check it yet, click the **Save** button, then **Cancel** button
25. Click **Noncompliances Tab** again
    - The noncompliance now appears in the grid
26. Click the **Printer icon**
27. Scroll down and **Review the Blocks** on the NR that are now complete

The NR number is randomly generated by PHIS. It is alpha numeric with 14 characters and always ends with the letter "N". The number that is generated does not relate to the establishment, e.g., it does not include the establishment number. The number will be followed by a / 1, 2 or 3 to indicate the number of pages to the NR. The noncompliant regulation(s) and the verification activity the IPP used to verify the regulations are listed. If a regulatory control action was taken the tag number appears in block 9. The description that the IPP entered on the Noncompliance page appears in block 10.

28. Click the **small X** at the top to close the tab or the pop up window that has the open NR
29. Click the **Edit icon (pencil)** to reopen the NR

When the IPP is satisfied with the written NR and ready to give a copy to establishment, he or she clicks the "Noncompliance Finalized" box. Once the IPP finalizes the noncompliance, the establishment can submit an NR appeal in PHIS if the establishment has access to PHIS.

30. Check the **Noncompliance Finalized** box on the bottom of the Noncompliance page
31. Click the **Save** button

When the noncompliance has been finalized, the save button is disabled which means IPP cannot make any additional entries unless they **unlock** the noncompliance

32. Click the **Cancel** button
33. Click the **Noncompliances Tab** again
    • Notice that the status of the Noncompliance has changed from Open to Finalized in the grid
34. Click the **Printer icon** again, print the NR, sign it, place copy in the government file, and give a copy to establishment management
    • You cannot print the NR during the training session
35. Click the **small X** at the top to close the tab or the pop up window that has the open NR

IPP finalize each noncompliance and present it to establishment management as soon as practical, even if they have not finished the inspection task. Although the NRs are stored electronically in PHIS, IPP maintain an "Open" and "Completed" NR file in the government office. NRs remain "open" until the IPP verifies that the establishment is back in compliance with the regulations that resulted in the issuance of the NR and has signed and dated block 15 and 16 of the NR. The establishment restored sanitary conditions, thus the establishment is back in compliance with the regulations.

36. Check the **NR Completed**
37. Click the **Save** button to set the NR status to "Completed"
38. Click the **Cancel** button to return to the Inspection Result page
39. Click the **Regulations Tab**
40. Check **416.15(a)** and **416.15(b)** as verified
    • You verified that the establishment implemented the required corrective actions
41. Check the **Inspection Completed** box

42. Click the **Save** button to set the status of the Inspection Task to "Completed"
    - The following message appears at the top of the page "Inspection Result saved successfully "
43. Click the **Close** button
44. Scroll down to the bottom of the task calendar
    - Notice that the Pre-op SSOP Review and Observation task is now green indicating that it is completed
45. Sign out of PHIS by clicking the **Red X** in the top corner of the screen

Summary Example

The following example summarizes documenting inspection results and *noncompliance* in PHIS. The documentation methods outlined in the example were demonstrated in the hands-on learning portion of this module.

Documenting Inspection Results and Noncompliance Example: Upon arrival at the establishment, the IPP logs in to PHIS and reviews the establishment task list and task calendar. The IPP notices that a Pre-Op SSOP review and observation task is on the task calendar to be performed today. The IPP "initiates/claims" (opens) the task by selecting "both" for the verification component. She clicks on the "regulations tab" and reviews the regulations that are mandatory for her to verify while performing this task. She determines the processing areas and equipment she will observe to verify compliance with the regulations. She enters the establishment to perform the task.

While performing the task, she finds meat, fat, and bone dust adhering to the surface of the band saw blade and on the inside of the band saw cabinet. She applies a U.S. Rejected Tag to the band saw and verbally notifies establishment management. She also finds dried, encrusted fat and meat scraps on the underside of two boning tables and notifies establishment management. She reviews the establishment's sanitation record. The establishment did not identify product residue on the band saw.

She returns to the inspection office to document the results of her verification. She logs on to PHIS, creates an NR, selects 416.13(a) and 416.4(b) to indicate noncompliance with those regulations, adds the description of the noncompliances to the NR by typing it in the NR text box, "finalizes" the noncompliance, and prints a copy of the NR to be given to the establishment. While she is documenting the noncompliances, the establishment cleans the band saw and the underside of the boning tables.

When she gives the NR to establishment management, the establishment requests that she remove the U.S. Rejected Tag from the band saw. She verifies that the band saw has been cleaned and removes the tag and verifies that the

residue from previous days' production has been removed from the underside of the boning tables. She also verifies that the establishment documented that it restored sanitary conditions in its records. Upon returning to the inspection office, she logs back into PHIS, documents the NR as "completed" and then documents the inspection task as "completed".

PHIS Steps for this Example

Activity	Monday			
SSOP Task	**Initiate**	1	**Complete**	6
NR	**Create**	2	**Complete**	5
Noncompliance	**Add**	3	**Finalize**	4

1. Initiate/claim the SSOP Task
2. Create the NR
3. Add Noncompliance (cite one or more Regulations)
4. Finalize Noncompliance (print, sign, and provide)
5. Complete the NR (after all verification performed/verifying return to compliance)
6. Complete the SSOP Task (after all results entered)

Attachment 1

When documenting noncompliance on a Noncompliance Record (NR), a good method to follow is to determine the 6Ws (While, When, What, Where, Who, and Why) and then document the details for each one of the Ws.

This is an example outline created using the 6W method. It is an organized way to gather facts and help prepare an NR.

While	While performing what inspection task? • Identify the scheduled inspection task • Provide brief summary of regulation(s) verified **Example**: "While verifying the construction requirement during the SPS verification task…..", or "While verifying the monitoring requirement during the HACCP Raw Intact task……"
When	When was the noncompliance discovered? • Date • Time • Operation status of the establishment When did the noncompliance begin? When has this noncompliance happened before? **Example**: While performing SSOP Pre-Op Review and Observation task on 8-20-13 at 7:44 a.m., after the facility was released for inspection, I discovered…
What	What is the noncompliance? What were the exact conditions? • Adulterant/contaminant- number, size, shape, color, and consistency. • Environment- leaks, condensation, wall or floor quality. What documents or records were reviewed? What regulatory control actions were taken, if any? What action did the establishment take or propose? A detailed description helps paint a picture for the reader, and makes pertinent and relative facts of the findings clear. **Example**: In the northeast corner of the meat processing room, I observed three dried meat particles (¼ inch by ¼ inch) laying on the surface of the

	meat grinder's knife assembly. I reviewed the establishment's pre-op sanitation records prior to my inspection; no sanitation failures were documented. **Note:** Words like filthy, dirty or scummy are not acceptable in describing noncompliant findings. The contamination must be accurately described with respect to size, shape and consistency, such as "2 inch by 5 inch smear of a black oily substance", or 15 to 20 1/4 inch to 1 inch pieces of fat.

Where	Specific location within the establishment?
	    • A room
	    • Area within a room
	    • Outside
	Other locations affected by the noncompliance?
	
	Example:
	In the northeast corner of the meat processing room, I observed…

Who	When a noncompliance is discovered, IPP have an obligation to immediately report it orally and then in writing to the establishment. Especially, when production is stopped and/or when meat, poultry or egg products are retained. **Example**: I immediately placed a U.S. Rejected Tag #B1234567 on the meat grinder and notified Ms. Rosenberg of the noncompliance and the reason for taking a regulatory control action.

Why	Why is there noncompliance?
	What regulations were not met?
	    • Regulation A
	    • Regulation B
	What procedure, plan or program was the establishment not following (e.g., Sanitation SOP, HACCP plan, or prerequisite program)?
	
	Example:
	I explained to Ms. Rosenberg, QC Manager, Quality Beef Co., that Quality Beef Co. is not following its Sanitation SOP dated on (4/20/2015), and signed by Sam Smith as written.
	
	Furthermore, it states on page 3, Section I-Pre-op Sanitation: "We will clean and sanitize all equipment before the start of meat processing operations."
	
	Lastly, I explained to Ms. Rosenberg the establishment is not meeting FSIS Regulation 416.13(a).