

PHIS INSPECTION VERIFICATION (PART 3)

Objectives

After completion of this module, the participant will be able to:

1. Correct an error in a finalized noncompliance.
2. State the purpose of associating NRs.
3. Identify the requirement for associating NRs.
4. Associate NRs in PHIS.
5. Identify inspection findings that must be discussed at the weekly meeting.
6. Create Meeting Agendas in PHIS.
7. State the purpose of the Memorandum of Interview (MOI).
8. Create a MOI in PHIS.

Associating NRs in PHIS

Purpose of Associating NRs

The purpose of associating NRs is to document that the immediate and further planned actions or the corrective actions and preventive measures the establishment implements are not preventing the recurrence of the noncompliance. In other words, there is a trend of noncompliance occurring in the establishment. The Agency may not be able to take further enforcement actions against the establishment unless the IPP has documented the establishment's inability to take actions that bring it back into compliance with the regulations. The NR associations documented by IPP are vital for the Agency to protect public health.

Determining if NRs should be Associated

After IPP document the noncompliance, they need to consider whether the noncompliance is an isolated incident or part of a developing trend. IPP should use professional judgment when making the determination whether NRs should be associated. IPP should gather information by asking questions, assess the information, and make a sound, supportable conclusion. Some factors that IPP should to consider are:

1. How much time has elapsed 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?

IPP are to associate NRs when they indicate an ongoing trend of **same cause** noncompliances or systemic problems with the same aspect of the establishment's food safety system.

The trend may be caused by the establishment's failure to implement its proposed preventive measures. Sometimes the establishment has implemented its proposed preventive measures; nevertheless, these measures are not effective in preventing the noncompliance from recurring. Frequently, SSOP or HACCP recordkeeping and corrective action NRs or SSOP or HACCP monitoring and corrective action NRs can be associated because they represent repetitive failure of the same aspect of the establishment's food safety system.

Note: If IPP are uncertain whether particular noncompliances should be associated, they are to request assistance from their supervisor.

NR Association Examples

The following examples represent situations when IPP should associate NRs and when they should not associate NRs.

NR Association Example 1: *The IPP issued an NR when he observed water dripping from the ceiling onto product in the production room due to the roof leaking on a rainy day (SSOP noncompliance). Three days later, he observes condensation (water) dripping from the ceiling onto product in the production room (another SSOP noncompliance). In both cases, water is the source of product contamination but the cause of the noncompliance is not the same (poor ventilation or air flow versus poor facility maintenance) so the IPP decides not to associate the NRs.*

NR Association Example 2: *The IPP issued an NR when she observed condensation dripping from the ceiling in the patty production room that was not contaminating product (SPS noncompliance). In block 12 of the NR, the establishment proposed adding another fan in the patty production room to*

improve air flow. Two weeks later, she observes condensation dripping from the ceiling onto patties on line one in the patty production room (SSOP noncompliance). She also notices that no additional fans have been installed in the patty production room. She concludes these two noncompliances are from the same cause (poor air flow or ventilation) and that the establishment did not implement the preventive measure to prevent recurrence of the noncompliance. She decides to associate the current NR to the previous NR.

Note: It is important that IPP realize that Sanitation Performance Standard (SPS), Sanitation SOP, or HACCP noncompliances may be associated when the cause of the noncompliance is the same as demonstrated in example 2.

NR Association Example 3: The IPP issued an NR when he observed that the establishment did not meet one of the recordkeeping requirements, there were no monitor's initials for one result. About five months later, he again observes that the establishment monitor did not initial one of the monitoring results. Although these two noncompliances demonstrate repetitive failures from the same part establishment's food safety system, the IPP determines that the establishment has shown a substantial period of compliance, and he decides not to associate this NR to the previous one.

NR Association Example 4: The IPP issued an NR for the establishment not performing a monitoring procedure as specified in the HACCP plan. Two weeks later she observes, at a CCP in a different HACCP plan, that the establishment does not perform the monitoring procedures as specified in the HACCP plan. She decides that the NRs demonstrate repetitive failures of the same part of the establishment's food safety system (not performing monitoring according to the HACCP plan) and that she should associate them in her documentation. She realizes she may associate these noncompliances even when they involve two different HACCP plans.

NR Association Example 5: The IPP issued an NR when she observed fecal material on a young chicken carcass while performing the poultry zero tolerance task. The establishment documented that the evisceration machine drawing spoons were out of adjustment, rupturing the intestines, and the eviscerating machine's rinse system was not working as the cause of the zero tolerance failure. The next day, she again observes fecal material on a young chicken carcass while performing the poultry zero tolerance task. This time the establishment documented the cause of the zero tolerance failure was the vent machine being out of adjustment. Although the establishment has documented two different causes for the zero tolerance noncompliances, the IPP decides to associate this NR to the previous NR because the underlying cause of the noncompliance is the same, i.e., the establishment has poor equipment maintenance procedures.

Procedures for Associating NRs

IPP use the “Noncompliances tab” on the Noncompliance page in PHIS to identify the previous NR that might be associated with the current NR. IPP click the arrow icon under the Link column for the NR and, then the “Maintain Associations” link. Search criteria such as key words in the description, the noncompliant regulation or task name can be entered to assist IPP in identifying NRs that may be associated. IPP may also review the printed copies of the NRs in the open and completed files in the government office.

To document a trend of noncompliance, the NRs **must be** associated as each noncompliance occurs, or as each NR is issued. The most recent previous NR with the same cause noncompliance should be associated. The IPP must associate this noncompliance to the current NR to establish the chronological history of the same noncompliance and ineffective preventive measures. If the IPP has been associating NRs in this manner (like adding a link to a chain), then it is not necessary to identify all of the previous associated NRs in block 6a of the current NR.

When IPP associate noncompliances, they:

- reference the previous NR number and the further planned action or the corrective action and preventive measures that were either not implemented or ineffective in preventing recurrence of the previous noncompliance in the description current noncompliance (block 10),
- record the reason for their decision to associate the noncompliances in the Inspection Notes in PHIS, and
- add the NR association as a discussion point to the weekly meeting agenda in PHIS.

Example Description for an Associated NR: *At approximately 10:16 a.m., while performing the Beef Sanitary Dressing task, I observed repeated instances, within a five-minute period, where the establishment’s employee hygiene practices (GMP 01- Employee Hygiene Practices-Knife Sanitation 3.5) associated with the removal of udders from the carcasses were not being implemented as written, resulting in carcass contamination. This section of the establishment’s GMP requires that the employee removing the udder sanitize the knife each time between carcasses. The employees removing udders did not sanitize their knives between each carcass. Two different employees were observed removing the udders from three carcasses before sanitizing their knives. I notified the Slaughter Supervisor of the employees’ failure to sanitize their knives between carcasses. A similar noncompliance was documented on NR # LIC9372041524N, dated 1/6/2016, in which employees failed to sanitize their knives after opening the hide. Retraining establishment employees to follow*

proper hygienic practices during the slaughter process and the written GMPs was ineffective in preventing recurrence of the noncompliance.

IPP **are to** discuss the identified associations between noncompliances and describe to establishment management why the associated NRs indicate a trend of noncompliance during the weekly meeting. Open communication with establishment management is an essential to part of the regulatory process. If IPP are not discussing repetitive noncompliance issues with the establishment, and thereby allowing them the opportunity to get the operation under control, IPP are not doing everything they can to ensure that the establishment is being provided “**due process**”. IPP are to document the discussion of noncompliance trends and NR associations in the Memorandum of Interview (MOI).

IPP should continue to associate NRs that are derived from the same cause **until they determine that an enforcement action is necessary** to bring the establishment into compliance with the regulations. The IPP’s documentation must show the development of a trend of noncompliance in order for the Agency to be able to support any recommendation for further enforcement action. When IPP believe that additional enforcement action is necessary, they contact the District Office through supervisory channels and request a Notice of Intended Enforcement (NOIE) be issued to the establishment in accordance with 9 CFR 500.4.

Maintaining NR Associations upon Rotation

When IPP rotate into a new assignment or are assigned to an establishment for the first time, they should review block 6a on the NRs in both the open and completed file to determine if a trend in noncompliance has been occurring in the establishment. They should pay particular attention to the immediate and further planned actions or corrective actions and preventive measures the establishment has been taking to address the noncompliances. This will help ensure that IPP continue to associate noncompliance from the same cause with previous NRs and the establishment continues to be notified of the failure to implement effective further planned actions to prevent the noncompliance from recurring.

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 03/06/15	2. RECORD NO. LIC1208122516N	3. ESTABLISHMENT NO. M38574+P38574
4. TO (Name and Title) QC Supervisor	5. PERSONNEL NOTIFIED Foreman	
6. RELEVANT REGULATIONS 416.13(a)		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM
8. INSPECTION TASK Preoperational SSOP	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION 9b. RETAIN/REJECT TAGS	
10. DESCRIPTION OF NONCOMPLIANCE At approximately 0400 hours after establishment pre-operational inspection and prior to start of production while performing preoperational SSOP review & observation task I observed rust and meat particles on three band saw blades stored on the boning table; rust, meat particles and a white residue on the food contact surfaces of the cuber. I applied US Reject tags # B1468923 and B1468924 to the blades and cuber parts respectively. I notified the foreman of the noncompliances and she initiated action to restore sanitary conditions. The regulatory control actions were relinquished when sanitary conditions were restored.		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>		
12. PLANT MANAGEMENT RESPONSE: The three band saw blades were disposed of. The sanitation crew soaked the cuber parts in acid solution to remove rust, meat specs and white residue. The SSOP will be modified to include a procedure for cleaning the saw blades in a manner that will prevent rust formation. A procedure will also be included for soaking the cuber in an acid solution. <i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>		
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE 03/06/15
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE 03/09/15

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 03/14/15	2. RECORD NO. LIC3408124916N	3. ESTABLISHMENT NO. M38574+P38574
4. TO (Name and Title) QC Supervisor		5. PERSONNEL NOTIFIED Foreman
6. RELEVANT REGULATIONS 416.13(a), 416.4(b)		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE
8. INSPECTION TASK Preoperational SSOP		9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION 9b. RETAIN/REJECT TAGS
10. DESCRIPTION OF NONCOMPLIANCE At approximately 0410 hours after establishment pre-operational inspection and prior to start of production I performed preoperational SSOP review & observation task. The following noncompliances were observed: 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 which is noncompliance with 416.4(b). I applied US Reject tags # B 1469277, B 1469278, B1469279, B 1469280, and B 1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws respectively. I notified the foreman of the noncompliances and she initiated action to restore sanitary conditions. After sanitary conditions had been restored, I relinquished the regulatory control actions.		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>		
12. PLANT MANAGEMENT RESPONSE:		
All items were cleaned and sanitized. The deficiency occurred because of the sanitation supervisor was not working last evening.		
The pre-op crew will be instructed to start pre-op monitoring 30 minutes earlier each day to provide them more time for inspection. The sanitation supervisor has been instructed to work more closely with the sanitation crew to ensure procedures are being appropriately implemented.		
<i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>		
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE 03/15/15
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE 03/17/15

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 03/20/15	2. RECORD NO. LIC4307125717N	3. ESTABLISHMENT NO. M38574+P38574
4. TO (Name and Title) QC Supervisor	5. PERSONNEL NOTIFIED Foreman	
6. RELEVANT REGULATIONS 416.4(b)		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) OR PREREQUISITE PROGRAM
8. INSPECTION TASK Preoperational SSOP	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION	
9b. RETAIN/REJECT TAGS		
10. DESCRIPTION OF NONCOMPLIANCE At approximately 0415 hours while performing the Pre-Operational Sanitation SOP Review & Observation task, the following was observed: Rust on the outer surfaces of the product brine tank; dried meat particles on the outer surface of the band saw cabinet; dried fat and meat particles on one of the legs of the boning table. The foreman was notified of the sanitation noncompliance. The foreman instructed the sanitation crew to initiate immediate corrective actions.		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>		
12. PLANT MANAGEMENT RESPONSE: No product was involved. The boning table, brine tank, and band saw were re-cleaned and sanitized immediately. All deficiencies were documented on the pre-op sanitation report. We will instruct the sanitation crew to check all pieces of equipment for rust and meat particles after cleaning. The sanitation foreman will assess the cleaning process for the equipment more closely.		
<i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>		
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE 03/20/15
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE 03/26/15

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 03/22/15	2. RECORD NO. LIC5606123921N	3. ESTABLISHMENT NO. M38574+P38574
4. TO (Name and Title) QC Supervisor		5. PERSONNEL NOTIFIED Foreman
6. RELEVANT REGULATIONS 416.13(a); 416.4(b); 416.1		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM
8. INSPECTION TASK Preoperational SSOP		9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION
9b. RETAIN/REJECT TAGS		
10. DESCRIPTION OF NONCOMPLIANCE At approximately 0412 hours after the establishment's pre-operational inspection and prior to start of production while performing the preoperational SSOP review & observation task, the following noncompliances were observed: Frayed plastic edges on four bone dust scrapers; rust on the blender arm and in the bottom of the hopper of the small Hobart grinder; rusty tenderizer needles; and rust on the hand contact surface of the edible product shovel. No sanitation records were available when the inspection task was performed. I placed US Rejected tags B 1472001, B 1472002, B 1472003, and B 1472004 respectively. I notified the foreman of the noncompliances and she initiated action to restore sanitary conditions. After sanitary conditions had been restored, I relinquished the regulatory control actions.		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>		
12. PLANT MANAGEMENT RESPONSE:		
The affected areas were re-cleaned and sanitized. The deficiency occurred due to lack of following procedures by the night manager. No product was adulterated due to the deficiency.		
The operations manager will re-address the importance of following the already in place procedures and completing the sanitation checklist. The production manager will check the room before the pre-op sheet is signed.		
<i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>		
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE 03/22/15
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE 03/23/15

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 03/28/15	2. RECORD NO. LIC5706123321N	3. ESTABLISHMENT NO. M38574+P38574
4. TO (Name and Title) QC Supervisor	5. PERSONNEL NOTIFIED Foreman	
6. RELEVANT REGULATIONS 416.13(a); 416.1		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM
8. INSPECTION TASK Preoperational SSOP	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION	
9b. RETAIN/REJECT TAGS		
10. DESCRIPTION OF NONCOMPLIANCE At approximately 0400 hours, I performed the preoperational review & observation task in the processing area. The inspection was done after the establishment's pre-operational sanitation inspection was completed. The following observations were made while performing this task: raw material (meat) particles were scattered on the metal wire guard of the packing machine; and an accumulation of raw material (meat) from the previous day's operation in the seams of the paddles and paddle cogs of the Hobart mixer. I took a regulatory control action on the packing machine and the Hobart mixer with US Reject B 1472103 and B 14721204 respectively. I notified the Foreman and after sanitary conditions were restored, I relinquished the regulatory control actions. The sanitation record was not available when this task was performed.		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>		
12. PLANT MANAGEMENT RESPONSE:		
<p>The areas found to be deficient were re-cleaned and sanitized before processing began for the day. The cause of the deficiency was a lack of training the sanitation crew and pre-op crew. No product was adulterated due to the deficiency.</p> <p>The sanitation crew has been trained on how to properly clean the areas in question and the night manager has been instructed to inspect these and other areas more thoroughly each night. To prevent recurrence we have done the above training and also require that our pre-op personnel check these areas specifically for the next 2 weeks.</p>		
<i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>		
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE 03/28/15
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE 03/30/15

Hands-on Activity

For the first part of this hands-on activity, you (as Robert Barclay) will document the results for a Heat Treated, Not Fully Cooked, Not Shelf Stable (HT-NFC-NSS) HACCP task because of a “stumble-on” noncompliance.

Note: “Stumble-on” means the IPP was not verifying the specific regulatory requirement as part of an inspection task but happened to observe noncompliance. The IPP must record the noncompliance under the appropriate inspection task.

Schedule the Heat Treated, Not Fully Cooked, Not Shelf Stable Directed Task to Document Noncompliance

IPP may need to schedule and perform a routine instance of an inspection task “as directed” based on conditions observed in the establishment. For example, the IPP may find noncompliance with a regulatory requirement verified under particular inspection task while performing a different task or other inspection duties.

1. Log into PHIS as **Robert Barclay (#)**
2. Click the **Task Calendar** option on the navigation menu
3. Filter on **Holland Point Foods** in the task list
4. Type **HACCP** in the Task Name box

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

5. Click the **Filter icon**
6. Click **Contains** from the pick list
7. Locate a task named **Heat Treated, Not Fully Cooked, Not Shelf Stable Task** with a start 2/1/2016 and end 2/29/2016
8. Click the **Add** link in the Directed column for the **Heat Treated, Not Fully Cooked, Not Shelf Stable** task
9. Type a “**1**” in the box for **Today’s date** in the calendar pop-up window

When IPP perform a directed instance of a routine task, they must enter a reason for performing the task as a directed task.

10. Click the drop down list arrow at bottom of the calendar pop-up window, then click **To Document Noncompliance** for the reason
11. Click the **Save** button

Entering Inspection Results for the Heat treated, Not Fully Cooked, Not Shelf Stable Directed Task

Before IPP enter results for an inspection task, they must select a verification activity or component (claim the task). PHIS implements this restriction.

12. Scroll down and Filter on **Robert Barclay** and **Holland Point Foods** in the task calendar
13. Scroll down and locate the **Heat Treated, Not Fully Cooked, Not Shelf Stable** HACCP task scheduled for **Today** on the calendar
14. Right-click on the 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

The “Task” tab on the Inspection Results page also has a data field for entering the reason for performing the task as a directed task.

15. Click the **Activity** tab
16. Click the **Square** in upper right corner of the pop box to maximize the screen
17. Click the radio button for the **Recordkeeping** verification component

There are five data fields relevant to HACCP verification tasks. The IPP should enter the HACCP plan(s), CCPs and any prerequisite programs that were verified while performing the HACCP verification task. If noncompliance is found, the HACCP plan(s), CCPs and prerequisite programs are listed in blocks 7 and 7a of the NR.

18. Click the drop down list arrow for the HACCP plan, then select **Smoked Product**
 - If the HACCP plan is not in the pick list, then type the name of the HACCP plan in the Other HACCP Plan box
19. Type **CCP 2B Stabilization** in the Name of HACCP CCP box

Note: The name of more than one CCP can be typed in the box

20. Click the **Save** button
 - The task is now claimed
 - A message at the top of the screen says “inspection result saved” successfully

IPP identify the specific regulations they verified during the performance of each inspection task. Highlighted regulations in the list must be verified or marked as “not applicable”. Other regulations in the list may be verified.

21. Click the **Regulations** tab
22. Check the **mandatory regulations** as verified- 417.2(c)4, c(5), c(6) and c(7); 417.4(a)2, 417.4(a)(2)(i, ii, and iii); 417.5(a)(1), (a)(2) and (a)(3); 417.5(b); and 417.5(c)

Note: For some inspection tasks, it may take more than one day for an IPP to verify all of the mandatory regulations. IPP may enter partial results on one day and continue finishing the task by entering additional results on subsequent days. Entering the regulations that the IPP has verified on a daily basis would very helpful to relief IPP or another IPP assigned to the establishment who may end up having to complete the inspection task. Recall that an IPP may have to reassign the task to himself or herself and complete it when an unforeseen issue arises. When the IPP that started the task has entered (checked) the regulations that have already been verified for the task, it provides a starting point for the IPP that has to finish the task. The IPP that is finishing the task does not have to duplicate work that has already been done.

IPP cannot complete the inspection task unless they have verified all on the mandatory regulations or marked the mandatory regulation as N/A (not applicable).

23. Check **417.4(a)(3)** as also verified
 - Non-mandatory regulations may be verified while performing the task

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.

24. Check the **Regulatory Non-Compliance** box

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

25. Click **Save** button
 - The Create/Edit NR button is now enabled
26. Click the **Create/Edit NR** button
 - The Noncompliance Page in PHIS is presented

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

27. Click the **Noncompliances Tab**
 - A blank noncompliance grid is displayed
28. Click **Add Noncompliance**
29. Check **417.4 (a)(2)(i)** as the noncompliant regulation

The noncompliance description needs to be 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.

30. Type the **Description**: “Direct observation verification not performed at the Stabilization CCP at the frequency written in the establishment’s plan”
31. Affected Product Information: Type **Sliced Bacon**
32. Select Addressed to: **Mike Adams**
33. Select Personnel Notified: **Diana Popadoupolis**
34. Notice the **NC Finalized** box but don’t check it yet, click the **Save** button
35. Click the **Cancel** button
36. Click **Noncompliances Tab** again
 - The noncompliance now appears in the grid
37. Click the **Printer icon**
38. 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. For HACCP verification tasks, the HACCP plan, CCP, and prerequisite program name will be listed. This information is generated from the information entered on the Activity tab on the Inspection Results page. The noncompliant regulation(s) and the verification activity the IPP used to verify the regulations are listed. The description that the IPP entered on the Noncompliance page appears in block 10.

39. Click the **small X** at the top to close the tab or pop-up window that has the open NR
40. Click **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.

41. Check the **Noncompliance Finalized** box on the bottom of the Noncompliance page
42. 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.

43. Click the **Cancel** button
44. Click the **Noncompliances Tab** again
 - Noncompliance status has changed from Open to Finalized
45. 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
46. Click the **small X** at the top to close the tab or 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.

If an IPP needs to make a change to a noncompliance that has been finalized, he or she must “unlock” it and provide a justification for making the modification.

47. Click **Edit icon (pencil)** to reopen the NR
 - The following message appears at the top of the page “This noncompliance has been finalized. To unlock it **click here** and provide a justification”.
48. Click the **Click Here** link at the top of the page
49. Click the drop down list arrow in the justification box and select **Correcting a Factual Error**
50. Type **Entered Wrong Regulation** in the **Reason to Edit NR** box
51. Click the **Unlock** button
52. You entered the wrong regulation, click the “**Box**” in front of 417.4 (a)(2)(i) to deselect it
53. Click the box in front of **417.4 (a)(2)(ii)** to select it

54. Check the **Noncompliance Finalize** box on the bottom of the Noncompliance page
55. Click the **Save** button

A grid at the bottom of the page lists the justification for modifying the noncompliance, the IPP's name that made the modification, and the date of the modification. Any additional changes made by the same IPP or another IPP will appear in the grid.

56. Click the **Cancel** button
57. Click the **Noncompliances** tab again
58. Click the **Print icon** again, print the **updated** NR, sign it, place a copy in the government file, and give a copy to establishment management

Note: The must give establishment management a copy of the updated NR.

59. Click the **small X** at the top to close the tab or the pop-up window that has the open NR
60. Click the **General tab**.

The IPP would associate the NR with a FSA, if the NR was created due to noncompliance found during an FSA. The IPP would associate a MOI with this NR if he or she was going to discuss the noncompliance at the weekly meeting.

Before the IPP can designate the NR as completed, the IPP must verify that the establishment has brought itself back into compliance the regulations that led to the issuance of the NR. ***If the NR is not checked completed, the IPP cannot complete the inspection task.***

61. Check **NR Completed** box
62. Click **Save** button
63. Click the **Cancel** button

Recall from the lecture portion of this module that the "Findings" tab on the Inspection Results page has two text areas that IPP may use for recording additional findings and comments directly related to performing the task.

64. Click the **Findings** tab
65. Enter comments and findings if needed
 - Specific production identification (lot), requirements verified at each CCP as they're verified and prerequisite programs verified, etc.
66. Check the **Inspection Completed** box
67. Click the **Save** button

Note: When the save button is clicked, the “Inspection Completed” box is disabled (grayed out). To make changes to an inspection task that has been completed, the IPP will need to “unlock” it, provide a justification, modified it, and re-save it.

68. Click the **Close** button

- Notice the task is green indicating that it has been completed

For the second part of this hands-on activity, you (as Robert Barclay) will document the results of a Fully Cooked, Not Shelf Stable HACCP verification task with a noncompliance observed and associate the NR with a previous NR.

Schedule the Fully Cooked, Not Shelf Stable Task

1. Scroll up and filter on **Holland Point Foods** in the task list (should be selected)
2. Type **HACCP** in the Task Name box (may still be filtered for HACCP)

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

3. Click the **Filter icon**
4. Click **Contains** from the pick list
5. Locate a task named **Fully Cooked, Not Shelf Stable Task** with a start 2/1/2016 and end 2/29/2016
6. Click the **Add** link in the routine column for the **Fully Cooked, Not Shelf Stable task**
7. Type a “1” in the box for **Today’s date** in the calendar pop-up window
8. Click the **Save** button

Before IPP enter results for an inspection task, they must select a verification activity or component (claim the task). PHIS implements this restriction.

9. Scroll down and Filter on **Robert Barclay** and **Holland Point Foods** in the task calendar (may already be filtered on Barclay and Holland Point Foods)
10. Scroll down and locate the **Fully Cooked, Not Shelf Stable task** scheduled for **Today** on the calendar
11. Right-click on the 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
12. Click the **Activity** tab
13. Click the **Square** in upper right corner of the pop box to maximize the screen

14. Click the radio button for **Both** verification components

There are five data fields relevant to HACCP verification tasks. The IPP should enter the HACCP plan(s), CCPs and any prerequisite programs that were verified while performing the HACCP verification task. If noncompliance is found, the HACCP plan(s), CCPs and prerequisite programs are listed in blocks 7 and 7a of the NR.

15. Click the drop down list arrow for the HACCP plan, then select **Deli Meat HACCP Plan**

- If the HACCP plan is not in the pick list, then type the name of the HACCP plan in the Other HACCP Plan box

16. Type **CCP 1B Cooking, CCP 2B Chilling, and CCP 3B Packaging** in the Name of HACCP CCP box

Note: The name of more than one CCP can be typed in the box

17. Click the “**Save**” button

- The task is now claimed
- A message at the top of the screen says “inspection result saved” successfully

IPP identify the specific regulations they verified during the performance of each inspection task. Highlighted regulations in the list must be verified or marked as “not applicable”. Other regulations in the list may be verified.

18. Click the **Regulations** tab

19. Select the **mandatory regulations** that were verified today, including **417.2(c)4, (c)5, (c)6 and (c)7; 417.4 (a)(2)(i), (ii) and (iii); 417.5(a)(1), (a)(2) and a(3), 417.5(b); and 417.5(c)**

There are several mandatory regulations for the HACCP verification tasks. Since IPP have to verify these requirements at all CCPs, the task will most likely take more than a day to complete. IPP may enter partial results for the task. When they find noncompliance before verifying all the mandatory regulations, they document it in PHIS and give the NR to establishment management as soon as practical. Refer to the example on page 38. When IPP find noncompliance, they are to document it on an electronically generated NR in PHIS.

20. Check the **Regulatory Noncompliance** box

- This enables the Create/Edit NR button

21. Click **Findings** tab

22. Enter the following information in the **Comments** box

- ▶ Oven Roasted Chicken Breast lot #A02042016
- ▶ Verified the HACCP requirements at both CCPs

- ▶ Verified implementation of the Allergen program
 - ▶ Need to verify that the establishment is back in compliance
 - ▶ Pre-shipment review needs to be verified
23. Click the **Save** button
 24. Click the **Create/Edit NR** button
 25. Click on the **Noncompliances** tab
 26. Click on **Add Noncompliance**
 27. Check **417.5(a)(3)** and **417.5(b)** as the noncompliant regulations
 28. For the Noncompliance Description, **Type:**
 - ▶ At approximately 10:00 am, on 2/8/2016, while performing a fully cooked, not shelf stable HACCP task, I reviewed the establishment's cooking record and noticed that the establishment monitor did not enter a time for one of the monitoring activities. I notified Chick Moreno, QC Tech., of the failure to record the time.
 29. Type **Oven Roasted Chicken Breast** in the "Affected Product Information" box
 30. Select **Mike Adams** for "Addressed To" name
 31. Select Personnel Notified: **Chick Moreno**
 32. Click the **Save** button to create the Noncompliance (within the NR record)
 33. Click the **Cancel** button to return to the General Tab of the NR page
 34. Click on the **Noncompliances** tab
 - The record keeping noncompliance appears in the grid
 35. Click the **Edit icon** (pencil) to reopen the recordkeeping noncompliance record
 36. Scroll down and check the **Noncompliance Finalized** box
 37. Click **Save** button
 38. Click **Cancel** button
 39. Click on the **Noncompliances** tab again
 40. Click on **Add Noncompliance**
 41. Check **417.2(c)(4)** as the noncompliant regulation
 42. For the Noncompliance Description, **Type:**
 - ▶ At approximately 1:00 pm, on 2/8/2016, while performing the fully cooked not shelf stable HACCP task, I reviewed yesterday's chilling record and noticed that the establishment only monitored the chilling CCP once in the morning and once in the afternoon. The HACCP plan states the monitoring activity is to be conducted every 2 hours. I notified Mary White, QC Tech., of the failure to monitor the CCP at the frequency stated in the HACCP plan.
 43. Type **Oven Roasted Chicken Breast** in the "Affected Product Information" box

44. Select **Mike Adams** for “Addressed To” name

The QC technician’s name (Mary White) is not on the personnel notified pick-list.

45. Type **Mary** in the first name box and **White, QC Tech** in the last name box

46. Click the **Add** button

The IPP should add Mary White as contact in the establishment profile otherwise he or she will have to manually type her name in the boxes each time she is notified of a noncompliance. After adding her as a contact, her name will appear in the pick-list.

47. Click the **Save** button to create the Noncompliance (within the NR record)

48. Click the **Cancel** button to return to the General Tab of the NR page

49. Click on the **Noncompliances tab** again

- The monitoring noncompliance appears in the grid
- Notice the NR number is the same but it has a “/ 2”

Associating NRs

IPP are to associate NRs when they indicate an on-going trend of **same cause noncompliances** or systemic problems with the establishment’s food safety system.

50. Click the **Link icon** (red arrow) for the monitoring (open) noncompliance

51. Click **Maintain Associations**

- No associated NRs appear in the grid

There are several filters that can be used on the Noncompliance Association page. The IPP may filter by “Any or All”, specify the NR date range, look for NRs that cite the exact same regulations, or NRs created for the same inspection task. IPP should be careful with their search criteria and the “Any or All” filter. If the IPP gets zero hits on the search, he or she can loosen his or her criteria and re-filter.

To ensure the IPP has the right NR to associate, the IPP may need to review the NRs issued to the establishment by clicking the **Printer icon** for each NR. After reviewing the recent NRs, the IPP can select the correct NR from the list to complete the association.

52. Check the **Box** next to the NR dated 2/2/2016

53. Click the **Save** button to create the association

- The associated NR now appears in the maintain associations grid

54. Click the **Back** button to return to the General Tab on the Noncompliance Page
55. Click on the **Noncompliances** tab
56. Click the **Edit icon (pencil)** to reopen the noncompliance record

Recall that the purpose of associating NRs is to document the establishment's unwillingness or inability to implement further planned actions or preventive measures to prevent the same cause noncompliance. In other words, the further planned actions or preventive measures the establishment takes is not bringing it back into compliance with the regulations. This documentation assists the Agency in taking additional enforcement actions against the establishment. The establishment must be given its "due process" rights.

57. **Type** the language for a developing trend in noncompliance in the description:
 - ▶ A similar noncompliance was documented on NR 0003023015296N, dated 2/2/2016. Counseling the monitor about conducting the monitoring activity at the frequency stated in the HACCP plan and having the HACCP coordinator review the monitoring record twice a day for 3 days did not prevent recurrence of the noncompliance.
58. Click the **Save** button to update the Noncompliance within the NR record
59. Click the **Cancel** button to return to the General Tab of the Noncompliance Record page
60. Click on the **Noncompliances** tab again
61. Click on the **Printer icon** for the noncompliance to view the NR (FSIS Form 5400-4) available for printing or saving as an electronic document
62. Review the **NR**, note the associated NR number in Block 6a and the updated trend language in block 10
63. Click the **small X** at the top to close the tab or the pop-up window that has the open NR
64. Click the **Edit icon (pencil)** to reopen the noncompliance record

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.

65. Scroll down and check the **Noncompliance Finalized** box
66. Click **Save** button
67. Click **Cancel** button
68. Click on the **Noncompliances** tab
 - NR Status changed to Finalized

After adding the language for a trend in noncompliance to the NR text, associating this NR to the previous NR, and finalizing the noncompliance, the IPP needs to print the NR and give a copy to establishment management.

69. In the establishment, you would now print the NR, sign it, place a copy in the government file and provide a copy to the establishment
70. Click **Cancel** button
71. Click the **Close** button
72. Sign out of PHIS by clicking the **Red X** in the top right corner of the screen

We are done, for now, with the NR documentation for this task and will now discuss the weekly meeting requirements, creating meeting agendas, and creating Memorandum of Interviews (MOIs). We will return to this NR and Inspection Results after we create some HACCP inspection notes, a meeting agenda, and a MOI. After that we will then pretend we held a weekly meeting with the establishment. After documenting that meeting and establishment management responses to our inspection issues and this NR, we will come back and document and complete the NR and Inspection Result for the Fully Cooked, Not Shelf Stable task.

PHIS Features IPP Use to Document Meetings between IPP and Establishment Management

PHIS has several time-saving features that IPP use to document the mandatory meetings that they have with establishment management. These features enable IPP to work efficiently. First of all, there is a meeting agenda tool for recording the topics to be discussed at the meeting. Secondly, there is an inspection notes tool to record IPP concerns that do not rise to the level of noncompliance but still need to be discussed with establishment management. The inspection notes can be easily transferred to the meeting agenda. Lastly, the Memorandum of Interview (MOI) tool creates the official record of the discussion between IPP and establishment management at each meeting.

Entrance Meetings

Upon rotation into an assignment, or when IPP are newly assigned to an establishment, they are to review the establishment's history, which is reflected in the ***establishment's homepage in PHIS***. They are to consult with their immediate supervisor if they have questions or concerns about the establishment's history. IPP need to review the following elements of the establishment's history.

1. PHIS records of recent noncompliances including any immediate and further planned action that the establishment may have provided to address the noncompliances;
2. Recent inspection notes and MOIs;
3. The results of any recent or ongoing FSIS verification sampling activities from the establishment's homepage;
4. The results from the most recent Food Safety Assessment(s) conducted at the establishment; and
5. If any enforcement action has been deferred, or if a suspension has been held in abeyance at the establishment. In addition, they need to familiarize themselves with the Agency's expectations, as described in the verification plan, and the results of the Agency's findings from verifying the effectiveness of the corrective and preventive measures that were proffered by the establishment. Finally, IPP are also to become familiar with the conditions that led the Agency to bring the enforcement action that has been deferred or resulted in the suspension that is in abeyance.

In addition to becoming familiar with the establishment's history, when IPP rotate into an assignment or conduct an inspection at an establishment for the first time, they are to review the:

1. establishment's Sanitation SOPs, HACCP plan, and prerequisite programs; and
2. establishment profile in PHIS to become familiar with the information in the profile. As IPP become familiar with the establishment operations, they are to update the PHIS establishment profile as needed.

After IPP familiarize themselves with establishment's history, HACCP plans, and programs, they are to conduct an **entrance meeting (e.g., the first weekly meeting)** with the establishment management. At this meeting, IPP should inquire about the specific operations of the establishment and seek to answer any questions that came up during their review of the establishment's history or programs. IPP are to ask establishment management about the location of the applicable records and the protocol for FSIS personnel to access and review the records. Establishments are required to provide access to records needed by IPP to perform their duties. However, IPP must review the necessary records in the location specified by establishment management. IPP are not to maintain any copies of the establishment's written programs or data from such programs in the inspection office. Likewise, IPP are to ask about any previously agreed upon notification (e.g., when IPP need to inform the establishment they will be collecting a sample) when Agency sampling is performed at the establishment.

IPP need to know this information so that an establishment can properly control sampled product pending FSIS test results.

IPP take notes at the entrance meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.

Awareness Meetings

When new regulations, policies, performance standards, compliance guidelines, or product sampling protocols are published in a Federal Register Notice, FSIS provides information, guidance and instructions to IPP for verifying the new policy or implementing the new performance standards or implementing the new sampling protocol through either a FSIS Directive or FSIS Notice. The directive or notice often directs IPP to conduct an awareness meeting with establishment management upon receipt of notice or directive. The notice or directive identifies specific information that IPP are to share with establishment management at the meeting.

IPP take notes at the awareness meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.

Weekly Meetings and Agenda Items

As set out in FSIS Directive 5000.1, IPP are to have weekly meetings with establishment management. IPP are to use the tools in PHIS to record inspection notes, create meeting agendas, document MOIs, and record the performance of weekly meeting tasks. The performance of the weekly meeting **AND** other meetings is documented in PHIS under the “Meeting with Establishment Management” task.

The purpose of the weekly meeting is to provide an opportunity for IPP to address matters that affect the establishment’s on-going compliance with FSIS requirements. The discussion of issues during the weekly meeting is not intended to replace documentation of noncompliance on an NR. Moreover, the fact that an issue is not discussed at the weekly meeting does not mean that the issue could not become the subject of an NR.

Meetings should benefit both IPP and the establishment. For instance, it is important that IPP discuss topics pertinent to the establishment’s food safety system that could affect public health. IPP are not precluded from asking establishments about any subject of regulatory concern, e.g. recalls, allergen control, etc. Establishment management may wish to share information regarding their operations, such as facility improvements and changes to their food safety systems, or express concerns at the meetings.

A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but that need to be brought to the attention of the establishment. For example, discussion of information from external sources, such as customer or consumer complaints, can provide information to alert establishment management about a safety risk or about other information that is relevant to the establishment's food safety system.

Note: FSIS Directive 5000.1 **requires** IPP to discuss developing trends in noncompliance at the weekly meetings and document the discussion of noncompliance trends and the associated NRs in an MOI. IPP are to discuss any identified associations between current and past noncompliances, and describe to establishment management why the associated NRs indicate a trend of noncompliance. It is recommended that IPP explain that continued noncompliance may result in further enforcement actions, to help the establishment understand the consequences of continued noncompliance.

FSIS Directive 5010.1 provides a **general list** of food safety related topics that IPP **may** consider discussing with the establishment during weekly meetings. Given the range of the issues confronting FSIS-regulated establishments, it may be difficult to discuss all of the topics that either FSIS or the establishment wishes to address during any one weekly meeting. Similarly, IPP should not use the list of topics in FSIS Directive 5010.1 like check list nor should they attempt to discuss all topics listed during a given period of time. The topics in the directive should be discussed as they arise. The list below is not all-inclusive. Possible topics for discussion listed in FSIS Directive 5010.1 include:

1. in-plant observations, e.g., individual NRs, less than perfect conditions that may, if not addressed, become noncompliances, and humane handling/poultry good commercial practices issues;
2. issues and information that the establishment wishes to share;
3. agency issuances, e.g., FSIS notices and directives and askFSIS questions;
4. information regarding FSIS sampling;
5. information related to the establishment's food safety system, e.g., changes to prerequisite programs used to support food safety decisions;
6. information from external sources, e.g., consumer complaints and recalls; and
7. any inspection related activities occurring outside of approved hours of operation.

On a periodic basis, about once a month as scheduled using the PHIS “Update Establishment Profile” task, IPP are to ask establishment management at the weekly meeting whether it has made any changes in the production process or other changes that could affect the safety of the product. If IPP learn that establishment management has made a change in its process, based on the nature of the change, IPP are to perform the appropriate verification activities outlined in FSIS Directives 5000.1 and 5000.6. If IPP are unsure how to proceed, they are to contact their supervisor for guidance.

Before the weekly meeting with the establishment, IPP may use the **meeting agenda tool** in PHIS to create an outline of the topics to be discussed. The topics discussed at the weekly meeting are dependent upon the events or conditions that occur in the establishment each week. The meeting agenda may be printed and distributed to IPP who will attend the meeting. IPP are to share a copy of the meeting agenda with establishment management when requested. PHIS will enable IPP to link the meeting agenda to an MOI to create an establishment meeting MOI.

When an establishment has multiple inspection shifts and/or multiple assigned IPP, it is the Inspector-in-Charge’s (IIC) duty and responsibility to conduct and document weekly meetings. The IIC:

- ensures that regulatory concerns that arise on all shifts are discussed at the weekly meetings,
- may delegate conducting the meeting to IPP,
- may include IPP (CSIs or FIs) in the meeting with establishment management;
- signs all documentation, and
- ensures that all IPP on all establishment shifts are made aware of regulatory concerns that are discussed at weekly meetings.

When the IIC designates an FSIS employee to conduct the weekly meeting, it **does not** mean that IIC never conducts the weekly meeting or attends the weekly meeting. Depending upon the events occurring (e.g., a product recall, positive pathogen result, humane handling issues or an inadequate HACCP system) or conditions observed (e.g., trends in noncompliance) in the establishment, it may be appropriate for the IIC, or even the FLS, to conduct the weekly meeting or at least be in attendance to assist and support IPP.

As set out in FSIS Directive 5000.1, IPP are to take notes at the weekly meetings and are to document the notes in a MOI in PHIS. IPP are to provide establishment management with a copy of the MOI.

Note: If IPP do not conduct a weekly meeting, they are to document this fact and the reason why in an MOI. For example, if establishment management chooses not to attend the weekly meeting, IPP are to document this in an MOI. If IPP cannot conduct the meeting due to the performance of higher priority tasks, such as sampling, IPP are to document this in an MOI.

For Cause Meetings

As needed, IPP can schedule a meeting with establishment management to discuss urgent issues such as a positive pathogen result, recall, outbreak, or inhumane handling incident.

IPP take notes at the meeting, document in a MOI in PHIS, and provide a copy of the MOI to the establishment.

Memorandum of Interview (MOIs)

FSIS Directives 5000.1 and 5010.1 and several notices instruct IPP to meet with establishment management and document the outcome of the meeting in an MOI. **An MOI is used to record and convey discussions with establishment or facility management.** The MOI is the written summary of an interview. It should not be a verbatim recitation of the interview, nor does it necessarily have to be written in the same order as the interview was conducted. Instead, it includes the date of the meeting, who was at the meeting, and captures and summarizes critical, relevant information including the specific topics discussed and answers to any questions asked during the meeting.

Note: IPP are not to use the MOI as a means to document daily conversations with establishment employees.

IPP can create and document the following MOIs in PHIS:

- Establishment Meeting
- Standard,
- Domestic Food Defense, and
- Import Food Defense

An MOI is a very important inspection tool for IPP because it documents the fact that IPP maintain open lines of communication with official establishments. For instance, after the weekly meeting, IPP are to prepare either an establishment meeting MOI or a standard MOI in PHIS to document the agenda items covered in the meeting and document any establishment responses. IPP are to document any discussion of noncompliance trends and NR associations at the weekly meeting in the MOI. Open NRs and NRs under appeal may be linked to an establishment meeting MOI or a standard MOI in PHIS.

An MOI can **also** document a variety of other issues including, but not limited to the:

- Discussion of a new inspection policy transmitted through a FSIS notice (e.g., a directed awareness meeting),
- Performance of records review in accordance with FSIS Directive 5000.2, and
- Performance of specific verification activities (e.g., supplier tracking information and humane handling) as deemed necessary by FSIS.

If establishment management provides no response to issues/concerns, this fact should be recorded in the MOI.

IPP are to maintain a copy of the MOI in the official government file and **must** provide a copy of the MOI to the establishment. When the MOI is provided to the establishment or facility, it is designated as “finalized” in PHIS.

MOIs can be used to track the establishment’s history of responding to issues/conditions in the establishment that are not noncompliance but can lead to noncompliance if conditions worsen or if the establishment doesn’t act upon the information the IPP has given the establishment, e.g., less than perfect execution of prerequisite program. If the situation has been documented in a MOI on numerous occasions, it would be hard for the establishment to say it didn’t know the issue/condition could lead to noncompliance when it finally results in noncompliance documented on an NR. The following example will demonstrate this concept.

MOI Example: *An establishment has concluded in its hazard analysis that the growth of pathogens is not likely to occur in its raw ground process because it implements a temperature control program. During the week the CSI found that the establishment missed a product temperature measurement as outlined in its temperature control program. The CSI realizes that one missed product temperature check is usually not enough evidence to conclude that the establishment does not have the documentation/records to support that the hazard is not reasonably likely to occur in the process. However, the CSI has found the same problem with temperature control program 6 times this month prior to the current finding, has discussed the failure to measure the product*

temperature at the weekly meeting, and documented the establishment's response in a MOI. Hence, the CSI concludes that the establishment is not executing the program as written and does not have documentation/records to support that the hazard is not reasonably likely to occur in the process, i.e., the establishment cannot support the decision in its hazard analysis, and there is noncompliance with 417.5(a)(1). By including the less than perfect execution of the prerequisite program in the weekly meeting and documenting it in an MOI, the CSI has given the establishment its due process. "Less than perfect conditions" documented in the MOIs can be referenced later in the NRs to support findings of noncompliance.

Note: *The determination that an establishment no longer has support for the decision made in the hazard analysis is not dependent upon a specific number of occurrences of failing to implement the prerequisite program. In this example, seven occurrences were used to represent the establishment's failure to execute its prerequisite program and maintain records that continue to support the decision it made in the hazard analysis.*

If IPP need assistance in determining whether or not the implementation of a prerequisite program and the records continue to support the decision that hazard is not reasonably likely to occur in its process, they should seek assistance through their supervisor.

If an establishment objects to any part of the MOI, IPP are to document the objection at the end of, or as an attachment to, the MOI. If the establishment's objection is in writing, IPP are to attach the written objection to the MOI. When the establishment's written objection is transmitted electronically, e.g., e-mail or other file format, IPP can upload the file in PHIS and save the document as an attachment to the MOI record. IPP provide a copy of the amended MOI to the establishment. MOIs can be reviewed by the Frontline Supervisor.

Tips for Writing MOIs

- Write the MOI as soon as possible after conducting the meeting. "Cold notes" are difficult to understand.
- Document who attended the meeting, the topics that were discussed, and what was said at the meeting. Document only the facts and not any opinions.
- Use quotations only when directly quoting a person.

Example: Mr. Adams said, "I told Ms. Popadoupolis, the Food Safety Manager, that the SSOP and HACCP records need to be available to the second shift inspector. " Ms. Popadoupolis said she would take care of it."

- Paraphrasing is generally a safer way of relating what someone said since it is difficult to capture the verbatim account when a person is speaking quickly.
- When paraphrasing, use words like “said” and “stated” to maintain a neutral tone.

Example: Mr. Adams stated that Mr. Wallace, the Maintenance Manager, is waiting for a quote to repair a large section of epoxy flooring outside the smokehouses and rack wash area.

- Do not use “claimed” as a synonym for “said” because this verb has an undertone of blame and mistrust.

Example: Mr. Wilson claimed he was not present during pre-operational sanitation inspection. (This sounds as though we do not believe him.)

- When discussing several people of the same gender, restate the name to prevent confusion.

Example: Mr. Irvine said that he told his Quality Assurance Manager that not making the SSOP and HACCP records available to the second shift inspector was a violation of the USDA regulations and that he will develop a method of making them available. (Who will develop a method of making the records available? Mr. Irvine or the Quality Assurance Manager?)

- Use the first person for your observations.

Example: I asked Mr. Irvine to tell me which office he contacted within the FSIS.

- Use the third person to relate information about the interviewee.

Example: Ms. Jones said she was the acting HACCP Coordinator of the establishment during the Food Safety Assessment.

Hands-on Activity

The following hands-on section is intended to provide familiarity and experience with the **Inspection Notes**, **Meeting Agenda** and **MOI pages** that are accessed from the Inspection Verification left navigation menu. The inspection notes, meeting agenda, and MOI process we will demonstrate support the weekly meeting.

For this hands-on activity, you (Robert Barclay) will:

- Create a few more inspection notes,

- Create a meeting agenda,
- Create a MOI, and
- Complete the Fully Cooked, Not Shelf Stable task you started

Creating Inspection Notes

The PHIS inspection notes feature is designed to be helpful to IPP in several ways: First of all, inspection notes help foster communication between IPP assigned to the establishment across days and shifts. Secondly, they provide a way to capture inspection findings that do not rise to the level of noncompliance but still need to be discussed with establishment management. Lastly, PHIS provides a mechanism for easily transferring these notes into a meeting agenda for the weekly meeting and MOIs.

1. Log into PHIS as **Robert Barclay (your #)**
2. Click the **Down Arrow** next to **Inspection Verification** in the left navigation menu
3. Click **Select Establishment** from the sub menu
4. Click the **radio button** to select **Holland Point Foods**
5. Click on **Inspection Notes** in the left navigation menu
 - The Inspector Notes List page and grid is displayed
6. Click the **Create Note** button
7. Check the **Enable Auto Save** box and select the “autosave content” for every 20 minutes
8. Populate data:
 - ▶ **Today’s** date (change if needed)
 - ▶ **First shift** radio button selected
 - ▶ Select **Processing** as the category
9. In the text box **Type**: “A cooler temperature check was not performed as written in the cooler temperature prerequisite program”

Note: A single missed activity (critical parameter measurement) for a prerequisite program usually does not result in a noncompliance determination. However, it is an issue that needs to be discussed with establishment management at a weekly meeting and documented in an MOI. The establishment’s continued failure to implement the program may eventually lead to a noncompliance determination. Verifying prerequisite programs will be discussed in the HACCP training modules.
10. Click the **Save** button and the **Cancel** button

11. Create and save an additional note with **Today's** date; select **Processing** as the category
 - ▶ I noticed the HACCP plan has been recently signed and dated, but I didn't observe any modifications
 12. Create and save an additional note with **Today's** date; select **Processing** as the category
 - ▶ Noncompliance on two NRs was associated because it is from the same cause: failure to monitor at the frequency stated in the HACCP plan
- Note:** IPP are required to document the identified trend in noncompliance in the **inspection notes feature** of PHIS for discussion at the next meeting with establishment management.

Creating a Meeting Agenda

FSIS Directive 5000.1 requires IPP to conduct entrance meeting and weekly meetings with establishment management. Some FSIS Notices require IPP to conduct an awareness meeting with establishment. Conditions in the establishment and some inspection findings may require IPP to have non-routine meeting with establishment management, e.g., a positive pathogen or positive residue sample result, humane handling issues, or a recall. These are often referred to as for cause meetings. A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but need to be brought to the attention of the establishment. IPP can use the meeting agenda tool in PHIS to create an agenda for the meeting.

13. Click on **Meeting Agendas** in the left navigation menu
 - The Agenda List page and grid are displayed
14. Click the **Create Agenda** button
15. Check the **Enable Auto Save** box and select the "autosave content" for every 20 minutes

The Agenda page is displayed which has 4 tabs. The default view for this page is the "Meeting" tab. The meeting date, meeting subject and attendees are mandatory information (red asterisk) that the IPP **must** enter on this tab. The IPP should also enter the meeting start time but this is not mandatory. The attendee names on the pick-list come from the contact names in the establishment profile. To select a meeting attendee name, IPP click (highlight) the person's name on the pick-list. To select multiple meeting attendee names from the pick-list, IPP hold down the "control" key on the computer key board and click the person's

name. Meeting attendee names not on the pick-list can be added by typing in the person's name and clicking the "Add" button.

The default meeting subject is "Establishment Awareness Meeting" but the IPP can manually change the subject title to:

- Reflect specific concerns like an *E. coli* O157: H7 Positive Sample Result/Positive Residue Result/Recall.
- Establishment Weekly Meeting or Entrance Meeting (when the IPP is newly assigned to the establishment)

Awareness meetings are conducted to inform industry of new FSIS regulations, policy, compliance guidelines and sampling protocols.

16. Populate data:

- ▶ Meeting Date: **Today's**
- ▶ Start Time: **1:00 p.m.**
- ▶ Change Subject: Type: **Establishment Weekly Meeting Agenda**
- ▶ Attendees: Select **Mike Adams** hold down the control key and select **Diana Popadoupolis**
- ▶ Type **Dr. James** in the first name box and **Davis, FLS** in the last name box
- ▶ Click the **Add** button to add the FLS

The PHIS agenda feature lets IPP select inspector notes and import those notes into a meeting agenda. This allows IPP to include appropriate entries from the PHIS inspector notes feature into a draft agenda in preparation for the weekly meeting. Some inspector notes may be memory joggers for the IPP or just to convey information to IPP assigned to the same establishment that may not need to be a discussion item at the weekly meeting with the establishment. When there are no inspection notes that need to be discussed at the weekly meeting, IPP will use the Agenda tab to add discussion topics to the meeting agenda.

17. Click on **Comment List** tab
18. Enter from **February 1** to **February 29** for the Date Range and click the **Filter** button
19. You can check the box for one or more notes, but for the exercise click the **Check All** button
20. Click the **Send Comments to Agenda Tab** button

Inspection notes are placed in the agenda "as is" and may need some editing and additions such as introduction and conclusion text before completing the meeting agenda.

21. **Edit** Inspector Notes into agenda items, as desired, e.g., change NR association note to:

- ▶ Discuss developing trend in monitoring noncompliance and the two NRs issued in the past week

22. **Add** a sentence to HACCP plan modification note:

- ▶ Ask establishment what modifications were made to the HACCP plan

IPP may add additional topics to the agenda that they did not enter in as inspector notes that they feel need to be discussed at the weekly meeting.

23. **Add** additional topics, e.g.,

- ▶ Discuss the training requirement for the person that modified the HACCP plan
 - Ask if the person that modified the plan successfully completed a course or training in the seven principles of HACCP that included a segment on the development of a HACCP plan and records review

If the IPP feels that a particular noncompliance on an open NR needs to be discussed with establishment management at the weekly meeting, IPP should associate the open NR with the meeting agenda.

24. Click the **NR** tab

25. Select the **Open NR** that identified the trend in monitoring noncompliance

26. To be sure you have selected the correct open NR, click the **View NR** button

27. Review the **Noncompliance Description**

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 **Save** button to create the meeting agenda

30. Click the **Cancel** button

31. Click the **Printer icon** for the weekly meeting agenda you created

32. Right click anywhere on the meeting agenda and select print in the pop up menu or click the printer icon at the bottom of the computer screen. Use the tools icon (sprocket) in the upper right corner to save it to your computer desktop (file, save as, file name, and save).

- The IPP should take the agenda to the meeting. He or she may distribute a copy to other IPP participants. IPP must share a copy of the meeting agenda with establishment management when

requested prior to the meeting. This will let the participants know what topics are going to be discussed at the meeting.

33. Click the **small X** at the top to close the tab or the pop-up window that has the open Agenda

Conduct the Meeting

Now that the IPP has created the establishment meeting Agenda, he or she would log off of PHIS and conduct the meeting. IPP use the Agenda to assist in the organization and focus of the meeting. IPP **are required** to take notes and document the outcome of the meetings they have with establishment management. An MOI is used to record and convey IPP discussions with establishment or facility management.

Creating an Establishment Meeting MOI from the Agenda

After the meeting, IPP document the outcome of the meeting on the MOI. IPP should include the establishment's response to regulatory and non-regulatory concerns discussed at the meeting.

34. Click on **Meeting Agendas** from the left navigation menu (**but we should already be at the Agenda list page**)
35. From the Agenda List, locate the meeting agenda you just created and click on the **MOI icon** (red arrow)
36. Click the **Enable Auto Save** box and select the "autosave content" for every 20 minutes

The Establishment Meeting MOI page is displayed which has 4 tabs: Meeting, Agenda, NR and Response. The default view for this page is the "Meeting" tab. The mandatory information (red asterisk), i.e., the meeting date, meeting start time, meeting subject, and attendees, is pre-populated in the fields with same information the IPP entered on the Agenda page.

The **Response** tab on the MOI Meeting page may be used by establishment management to record comments/responses to the topics discussed at the meeting in PHIS when the establishment has a Plant Manager role (eauthentication) in PHIS. PHIS will automatically add their comments, any rebuttals, or additional information to the finalized MOI. **IPP are not to add establishment responses using the Response Tab.** This tab is reserved for an establishment that has a Plant Manager role in PHIS and wants to respond to a **finalized MOI**. If the establishment does not have a Plant Manager role but chooses to respond electronically, e.g., e-mail or other file format, to meeting issues there is "**Add Attachment**" link at the bottom of the Agenda tab of the Establishment Meeting MOI page to upload the file.

Note: If the IPP creates an MOI using the left navigation menu rather than through the Agenda List page, there *is not* an “Add Attachment” link for uploading electronic documents.

If the establishment does not provide a response to a discussion topic that requires a response, IPP are to document the establishment’s failure to respond in the MOI. If the establishment objects to any part of the MOI with a **handwritten response (or other hardcopy)**, IPP are to attach the handwritten objection to the MOI hardcopy in the government file. IPP are not to transcribe the establishment’s written response into PHIS. When the establishment’s written objection is transmitted electronically, e.g., e-mail or other file format, IPP can upload the file in PHIS and save the document as an attachment to the MOI record using the “Add Attachment” link at the bottom of the Agenda tab of the Establishment Meeting MOI page.

37. From the **Meeting tab**, update any information that changed from the agenda, e.g., attendee names, date, or time
38. Click on the **Agenda tab**
39. Edit the text to create a record of the meeting from the agenda topics, e.g., add the following to the developing trend in monitoring noncompliance:
 - ▶ Mr. Adams said both incidents will be immediately investigated to determine why monitoring is not being performed at the required frequency. A QC tech will review monitoring records twice a day for a week.
40. Add the following to the developing trend in monitoring noncompliance:
 - ▶ I informed Mr. Adams that continued failure to meet these regulatory requirements may result in additional regulatory or administrative action.

Note: When there is a trend in noncompliance occurring in the establishment, IPP are required to include this statement in the MOI. This statement is another means of providing the establishment due process.
41. Click the **Save** button to create the Establishment Meeting Minutes MOI
42. Click the **Cancel** button
43. To view a formatted copy of the Establishment Meeting MOI, locate the establishment meeting minutes MOI you created
 - ▶ By Date (Today’s)

► By Type (“Establishment Meeting MOI”)

The IPP should look at the printed or PDF version of the MOI to make sure it is complete and has no errors. It’s also a good idea for the IPP to give the copy of the MOI to the establishment before he or she designates it as final. Any establishment disagreement with the contents can be addressed before the MOI is final. The MOI may be edited after it is finalized in PHIS by unlocking it and providing a justification like the NR. The history of edits made to unlocked finalized MOIs is documented and displayed to IPP and establishment managers that have eAuthentication.

44. Click on the **Printer icon** to view the MOI record available for printing or saving as an electronic document
45. Click the **small X** at the top to close the tab or pop-up window that has the open MOI
46. Click the **Edit icon (pencil)** to edit the MOI you created
47. Scroll down and check the **Finalize** box
48. Click the **Save** button
 - The MOI status is now “Finalized” in the MOI List page grid.

The IPP **must** give a copy of the finalized MOI to the establishment. Several example MOIs are in Attachment 1 of this handout.

Completing the Fully Cooked, Not Shelf Stable Task

For this hands-on activity, you did not find additional noncompliance and you verified that the establishment is back in compliance with the monitoring requirement. PHIS will not allow the inspection task to be designated as “complete” until the IPP documents the NR as “complete”.

In reality it would probably take the IPP a few days to verify that the establishment is conducting the monitoring activity as written in the HACCP plan. Thus, the IPP would likely update the inspection results on a subsequent day. But in the training session we want to demonstrate how to complete an inspection task.

49. Click the **Inspection Results** from left navigation menu
50. Click on **Edit icon (pencil)** for the open Fully Cooked, Not Shelf Stable HACCP verification task
51. Click the **Create/Edit NR** button to access the NR
 - The Noncompliance Record page is displayed
52. Check the **NR Completed** box
53. Click the **Save** button to set the NR status to “Completed”
54. Press the **Cancel** button to return to the Inspection Result page

PHIS will not allow inspection tasks to be designated a completed unless all the mandatory regulations are either verified or marked as N/A (Not Applicable). N/A is provided for mandatory regulations that, for some unavoidable reason or unforeseen circumstances, could not be verified during the execution of the inspection task or the regulation does not apply to establishment operations.

55. Click on the **Regulations** tab
56. Update the task End Date with **Today's Date** if necessary
57. You also verified **430.4(a), 430.4(c)(2), 430.4(c)(3), and 430.4(c)(7)** and the pre-shipment review. The establishment is in compliance with these regulations.
 - Lm requirements are discussed later in the course

You have ensured the establishment is back in compliance with the regulations sited in the NR.

58. Click the **Findings** tab
 - Update the information, e.g., indicate all mandatory regulations verified
59. Check the **Inspection Completed** box
60. 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 "
61. Click the **Cancel** button
 - Notice the status of the inspection task changes to "completed" in the grid
62. Sign out by clicking the **Red X** in the upper right corner of the screen

This ends the hands-on learning for Inspection Verification. You will get more practice using the Inspection Verification elements in several workshops during the rest of the course.

Summary Example

Documenting Inspection Results and Noncompliance Example: Upon arrival at the establishment, the CSI logs in to PHIS and reviews the establishment task list and task calendar. The CSI notices that a Not Heat Treated- Shelf Stable HACCP verification task is scheduled to be performed today. The CSI opens (claims) the task by selecting the component used to verify the regulatory requirements. He clicks on the “regulations tab” and reviews the regulations that are mandatory for him to verify while performing this task. He selects a specific production of beef pepperoni. He enters the establishment to perform the task. While verifying the monitoring, verification, and recordkeeping regulatory requirements at the fermentation step-CCP 1, he determines that the establishment is not following the monitoring procedure as written in the HACCP plan. He informs establishment management of the noncompliance. Upon returning to the inspection office, he logs in to PHIS, creates an NR, selects 417.2(c)(4) to indicate noncompliance with that regulation, and adds the description of the noncompliance to the NR by typing the monitoring noncompliance in the NR text box. He “finalizes” the noncompliance, prints it, and delivers it to establishment management. Three days after documenting the monitoring noncompliance, he observes the monitor performing the monitoring procedure at the fermentation step for another lot of beef pepperoni. This time the monitor followed the procedure as written in the HACCP plan. He notes that the establishment has brought itself back into compliance with the monitoring requirement.

Fourteen days after starting the task while verifying the monitoring, verification, and recordkeeping regulatory requirements at the drying step-CCP 2, he notices that an entry on the monitoring record was not initialed. He notifies the establishment of this noncompliance. He logs in to PHIS, selects the same inspection task, and documents a second noncompliance on the NR. He selects 417.5(b) to indicate noncompliance with that regulation, **ADDS this recordkeeping noncompliance to the existing (open) NR by typing the finding in the NR text box, “finalizes” the second noncompliance, and prints another copy of the NR to give to the establishment.**

Two days after documenting the recordkeeping noncompliance, he reviews the establishment’s monitoring records for product lots produced after the beef pepperoni and finds that all the entries have been initialed. He notes that the establishment has brought itself back into compliance with the recordkeeping requirement.

After verifying the establishment’s prerequisite programs and all relevant regulations including the pre-shipment review for the specific production, he logs in to PHIS, indicates that 9 CFR 417.5(c) was verified, changes the status of the NR to “completed”, and then documents the inspection task as “completed”.

PHIS Steps for this Example

Activity	Day 1	Day 4	Day 14	Day 16	Day 17
HACCP Task	Claim 1	<i>Open</i>			Complete 7
NR	Create 2	<i>Compliance Verified</i> → 5			Complete 6
1 st Noncompliance	Add/Finalize 3	<i>Finalized</i>			
2 nd Noncompliance			Add/Finalize 4	<i>Finalized</i>	

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

Attachment 1: Example MOIs

Memorandum of Interview Conducted at EST. M44925/P44925 Weekly Meeting

Date: February 4, 2016

Time: 1300

Attending: Mr. Mike Adams, President
Ms. Diana Popadoupolis, Food Safety Manager
Mr. Chick Moreno, HACCP Coordinator
Mr. David Wallace, Maintenance Manager

Inspector Conducting the Meeting: Mr. Robert Barclay, Consumer Safety
Inspector/IIC

Items Discussed:

1. Noncompliance Records

I reviewed the condensation noncompliance documented on NR #LIC4709025117N issued this week with establishment management. I informed the establishment that I associated this condensation noncompliance with the condensation noncompliances documented on NR # LIC2946085063N and NR # LIC9372041524N and that installing a fan in the hot dog packaging room did not prevent the noncompliance from recurring. I also informed establishment management that continued failure to meet the regulatory requirements may result in additional regulatory or administrative action. Mr. Adams stated that Ms. Popadoupolis would modify the Sanitation SOP to include a procedure for a production employee to observe all overheads in production areas and remove condensation as necessary during operation.

2. Implementation of the Temperature Control Program

I informed establishment management that when I reviewed the records associated with their temperature control program this week I found that the program was not being implemented as written. I noted that one product temperature measurement was not recorded. Mr. Moreno stated that he would counsel the responsible employee on the importance of taking the temperature measurements at the frequency stated in the program. Ms. Popadoupolis stated she would review the internal temperature logs daily for one week starting Monday.

3. Lockout/Tagout

I inquired about the status of the establishment's updated list of lockout/tagout trained employees. Mr. Wallace stated that the list is in the process of being updated and as soon as it is completed, the list will be forwarded to me.

4. Safety

I informed establishment management of the near miss that occurred earlier this week involving an establishment employee riding an electric pallet jack and myself.

Mr. Moreno responded by stating that he would look into the incident and Mr. Wallace stated that all electric pallet jacks have had the rabbit function (make the jack go faster) disconnected.

5. Record Access

I informed establishment management that they must make their SSOP, HACCP, and all supporting documentation accessible to the 2nd shift inspector. I informed establishment management that the failure to make these records accessible would result in the inspector issuing a noncompliance record. Mr. Adams responded by stating that plant management will discuss this matter and one of the possible solutions would be to provide a key to the night shift supervisors.

6. HACCP

Ms. Popadoupolis informed me that she reassessed the establishment's RTE product HACCP plans to clearly define the establishment's critical limits as per the askFSIS questions listed below that were discussed at the previous meeting.

Question: When the establishment decides to use [Appendix A Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products](#) as its supporting document (9 CFR 417.5(a)(2)) for its cooking/lethality step, must it identify one specific time/temperature parameter that it will use as its critical limit in its HACCP plan or can the establishment use the entire table?

Question: If the establishment is producing several different products under a single HACCP plan, can the establishment provide a list in its HACCP plan of the time/temperature parameters that it may use from [Appendix A Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products](#) as a critical limit?

Ms. Popadoupolis also stated that the establishment was going to begin producing sliced cooked beef and were in the final stages of preparing the HACCP plan.

7. Planned Improvement Program

Mr. Wallace reviewed the establishment's PIP. Mr. Wallace stated that plant management is awaiting a possible solution from the rack manufacturer regarding the flaking paint on the metal racks used to store rework plastic tubs.

Mr. Wallace stated that plant management is waiting for a quote to repair a large section of epoxy flooring outside the ovens and rack wash area. Mr. Wallace stated that permanent repairs to this section of the floor may not be completed until November. However, in the mean time, the maintenance personnel will be performing minor repairs as necessary.

I informed Mr. Wallace that several lights were out in the formulation room and some were out in the sliced product packaging room. Mr. Wallace stated that the lights would be replaced this weekend.

8. Holiday Operations

I inquired if the establishment would be conducting operations on Monday, February 21st (Federal Holiday). Mr. Adams responded and stated that the establishment would conduct normal operations on that Monday. Mr. Adams asked if he needed to provide a letter to that effect and I responded by stating that establishment management needed to provide a letter to the USDA indicating that the establishment will be operating and include the hours of operation.

9. Review of Establishment Records

I discussed with Mr. Adams the list of establishment records that I had reviewed earlier in the week, including sanitation food contact surface and environmental swab results from 2-1 through 2-3.

Plant Management was provided a copy of the meeting notes.

Example Memorandum of Interview (MOI) Awareness Meeting

Date: October 17, 2019

Time: 1445

Location: Novosibar Poultry, INC. EST. P44926
1000 Country Lane
Livingston, CA 00000

Attending: Ms. Irene Jones, HACCP Coordinator

Inspector Conducting the Meeting: Cindy Soundly, CSI

Subject: FSIS Notice 08-10 dated 10/17/19 titled "Sampling of Young Chicken Carcasses for Nitrofurans Prior to Chilling"

The following program points were discussed during the awareness meeting:

1. FSIS developed the nitrofurantolamide residue sampling project to identify metabolites of nitrofurantolamide, including semicarbazide (SEM) in poultry carcasses.
2. The sample for the study is a young chicken whole carcass. The carcass will be collected at a point in the production line immediately after evisceration and prior to chilling and the application of antimicrobial agents.
3. The sample will be collected under the project code NRP_WC (NRP – Whole chicken) and will begin on or after November 1, 2019.
4. The sample will be collected and shipped on the same day to the FSIS Western Laboratory for analysis using the nitrofurantolamide method.
5. The establishment is not required to hold the production lot pending laboratory results for the sample collected for this sampling project.
6. FSIS will report the test results through PHIS.
7. Poultry slaughter establishments eligible for NRP_WC testing will continue to receive other directed residue sampling tasks under the U.S. National Residue Program (NRP).

Ms. Jones was provided a copy of the awareness meeting notes.

**Example Memorandum of Interview (MOI) Presumptive *E. coli* O157:H7
Positive**

Date: February 14, 2015

Time: 0730

Location: Groveton Meats, Inc.
1200 Presley Drive
Los Angeles, CA 94852

Attending: Ms. Haley Craig, HACCP Coordinator
Mr. Lauren Kennedy, Plant Manager

Inspector Conducting the Meeting: Mr. Robert Barclay, Consumer Safety
Inspector/IIC

Subject: Presumptive positive *E. coli* O157:H7 ground beef sample

Items Discussed:

1. *E. coli* O157:H7 Presumptive Positive Result

I notified Ms. Craig and Mr. Kennedy that the routine MT43 ground beef patty sample that I submitted to the FSIS lab on 1/31/11 tested presumptive positive for *E. coli* O157:H7.

2. Affected Product

The review of establishment records revealed that the amount of product represented by the sample was 900 lbs of ground beef patties. Ms. Craig stated that the 900 lbs was still on QC hold in the main freezer, this I later confirmed myself. The source material was 2513 lbs of beef trimmings which is now implicated in the presumptive positive pathogen result (bill of lading #25799 lot #012711AJ). I asked Ms. Craig to identify the additional product lots that were produced using the same lot of beef trimmings. Ms. Craig stated that he believed that a lot of beef patties and hamburger patties were also produced, and he would provide me with the amount of product and the lot numbers. Ms. Craig also stated that Groveton does not commingle lots of beef trimmings received from Open Beef, Inc., and

that a total clean-up is performed before a new lot of beef trimmings is used.

3. Possible Additional Enforcement Action

I informed Mr. Kennedy and Ms. Craig that if the sample is confirmed positive for *E. coli* O157:H7, the product would be considered adulterated and the establishment would be expected to take corrective actions including proper disposition of the held product. FSIS may take withholding action or suspend operations in accordance with the Rules of Practice, Part 500 of the MPI regulations if adulterated product moves in commerce

Supplier Information Previously Gathered:

1. Establishment Name and Number: Open Beef, Inc., Est. M44927
2. Establishment phone number: 707-777-1000
3. Establishment point of contact: Jeff Irvine, Food Safety Manager
4. Supplier lot number: 012711AJ
5. Raw beef component: beef manufacturing trimmings
6. Amount of raw beef component: 2513 lb

The establishment was unable to provide the point of contact's E-mail address and fax number and the production date for the beef trimmings.

Establishment management was provided a copy of the meeting notes.