



**Public Health Information System:
Industry Session**

Inspection Verification Features

- *Inspection Results*
 - *Noncompliance*
 - *Inspector Notes/Agendas/MOIs/NR Appeals*
-

Inspection Verification Features









- Inspection Results
- Noncompliance Records
- Inspector Notes
- Meeting Agendas
- Memorandum Of Interview (MOI)
- Correspondence

Inspection Verification Menu – Inspection Results

You are here: Home > Domestic Inspection > Inspection Results List

Inspection Results

Holland Point Foods
M38572+P38572

Task Name	Start Date	Inspector	IR Number	Status	Edit	Delete
Fully Cooked Not Shelf Stable HACCP Verification	2/2/2011	Robert Barclay	LIC2412023902I	Completed		
Operation SSOP - Review and Observation	1/28/2011	Robert Barclay		Completed		
Pre-Operational Recordkeeping	1/28/2011	Robert Barclay		Completed		
Fully Cooked Not Shelf Stable HACCP Verification	1/1/2011	Robert Barclay	LIC1811012101I	Completed		

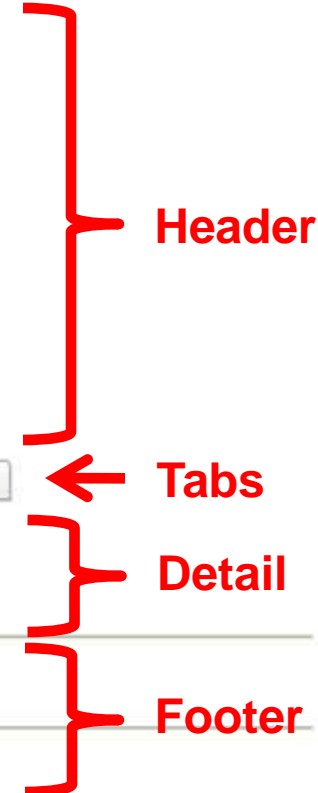


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Inspection Results

Open Beef, Inc
M38574

Inspection Result#:	VPP0012122314	Status:	Hot Opened
Start Date *:	<input type="text" value="2/1/2011"/>	Create Date:	<input type="text" value="12/14/2010"/>
End Date *:	<input type="text" value="2/28/2011"/>	Update Date:	<input type="text"/>
Type of Inspection:	Humane Handling and Good Commercial Practices		
Task Name:	Livestock Humane Handling Verification		
Inspector Name:	Robert Allen		
Concern:	Food Safety		



- Task
- HATS
- Vul.Pts
- Dataset
- Activity
- Regulations
- Findings
- Qnaire

Reason for Directed Task:

Reference Reason ID:

Inspection Completed

- Save
- Create/Edit MOI
- Create/Edit NR
- Cancel
- Close

Open Beef, Inc
M38574

Inspection Result#: VPP0012122314I **Status:** Not Opened
Start Date *:  **Create Date:**
End Date *:  **Update Date:**
Type of Inspection: Humane Handling and Good Commercial Practices
Task Name: Livestock Humane Handling Verification
Inspector Name: Robert Allen
Concern: Food Safety

Description	Verified	Duration (Min/Hrs)
Adequate Measures for Inclement Weather	<input type="checkbox"/>	<input type="text" value="(select)"/>
Truck Loading	<input type="checkbox"/>	<input type="text" value="(select)"/>
Water and Feed Availability	<input type="checkbox"/>	<input type="text" value="(select)"/>
Handling During Ante Mortem Inspection	<input type="checkbox"/>	<input type="text" value="(select)"/>
Handling of Suspect & Disabled	<input type="checkbox"/>	<input type="text" value="(select)"/>
Electric Prodding / Alternative Object Use	<input type="checkbox"/>	<input type="text" value="(select)"/>
Observation for Slips & Falls	<input type="checkbox"/>	<input type="text" value="(select)"/>
Stunning Effectiveness	<input type="checkbox"/>	<input type="text" value="(select)"/>
Check for Conscious Animals on the Rail	<input type="checkbox"/>	<input type="text" value="(select)"/>

Inspection Completed

Inspection Results

Open Beef, Inc M38574

Inspection Result#: VPP1215123314I

Status: Not Opened

Start Date *: 12/14/2010 

Create Date: 12/14/2010

End Date *: 12/14/2010 

Update Date:

Type of Inspection: Food Defense

Task Name: Storage Areas

Inspector Name: Robert Allen

Concern: Food Safety

Task HATS **Vul.Pts** Dataset Activity Regulations Findings Qnaire

Vulnerable Points	Verified
Evidence of Possible Tampering on Stored Product	<input checked="" type="checkbox"/>
Unrestricted Access to Dry Ingredients	<input checked="" type="checkbox"/>
Unrestricted Access to Raw Product Ingredients	<input checked="" type="checkbox"/>
Unrestricted Access to Finished Product	<input checked="" type="checkbox"/>
Unrestricted Access to/use of Hazardous Chemicals	<input type="checkbox"/>

Inspection Completed

Save Create/Edit MOI Create/Edit NR Cancel Close

Documentation Policy – HACCP Information

- The HACCP plans, CCPs, products that IPP verify are now documented
- How IPP verify regulatory requirements (i.e., review and observation or recordkeeping) is now documented




Holland Point Foods


M38572+P38572

Inspection Result#: LIC4209031231I

Status: Open

Start Date *: 3/31/2011 

Create Date: 3/31/2011

End Date *: 3/31/2011 

Update Date: 3/31/2011

Type of Inspection: Fully Cooked Not Shelf Stable HACCP


Task Name: Fully Cooked Not Shelf Stable HACCP Verification

Inspector Name: Robert Barclay

Concern: Food Safety

Task HATS Vul.Pts Dataset **Activity** Regulations Findings

Qnaire


HACCP Plan: Deli Meat HACCP Plan 



Other HACCP Plan:

Name of HACCP CCP(s): 2B Stabilization



Prerequisite Program: (select) 

Other Prerequisite Program:

Verification Activity *: Review & Observation Record Keeping Both



Documentation Policy – Regs Verified



- IPP will identify what regs were verified during the procedure
- “Mandatory” regs must be verified in order to complete the inspection task

Open Beef, Inc
M38574

Inspection Result#: VPP0012122314I

Status: Not Opened

Start Date *: 2/1/2011 

Create Date: 12/14/2010

End Date *: 2/28/2011 

Update Date:

Type of Inspection: Humane Handling and Good Commercial Practices

Task Name: Livestock Humane Handling Verification

Inspector Name: Robert Allen

Concern: Food Safety

Task	HATS	Vul.Pts	Dataset	Activity	Regulations	Findings	Qnaire
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Paragraph	Paragraph Description	Mandatory	Verified	N/A
313.1	Livestock pens, driveways and ramps	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
313.2	Handling of livestock	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>
313.5	Chemical; carbon dioxide	No	<input type="checkbox"/>	<input type="checkbox"/>
313.15	Mechanical; captive bolt	No	<input type="checkbox"/>	<input type="checkbox"/>
313.16	Mechanical; gunshot	No	<input type="checkbox"/>	<input type="checkbox"/>
313.30	Electrical; stunning or slaughtering with electrical current	No	<input type="checkbox"/>	<input type="checkbox"/>
313.50	US Rejected tags shall not be removed by anyone other than an inspector	No	<input type="checkbox"/>	<input type="checkbox"/>

Regulatory Non-Compliance



Documentation Policy – Corrective Actions



416.15 or 417.3

- When IPP document compliance with corrective actions, they are to include a brief description of their observations that support a finding of compliance
- Record these affirmative findings in the text box (Inspection Results Findings tab)

Task HATS Vul.Pts Dataset Activity Regulations Findings


Qnaire

Non-Regulatory Concerns Product Adulteration


HACCP Code: 03G - Fully Cooked - Not Shelf Stable

Sample Form Number:

Affirmative Findings



Establishment identified the cause of the deviation to be a short in the cooler fan motor. The cooler fan motor was replaced. The establishment implemented a maintenance program for the coolers. All product was held. The establishment used the Combase *Perfringens* predictor computer modeling program to evaluate the cooling deviation. Results indicated no growth of *C. botulinum* and less than 1 log growth of *C. perfringens*



What is Noncompliance (NC)?

- Failure to meet a regulatory requirement
- IPP are to:
 - Notify the establishment orally and in writing of any NC found in a timely manner
 - Document NC on an NR in PHIS
 - Give the NC/NR to establishment
 - Verify establishment brings itself back into compliance

Noncompliance (NC)

- Only **one NR** is completed per inspection procedure, but **more than one noncompliance** with a regulation or regulations can be documented on that one NR
- Thus, there may be multiple pages to one NR. Each page documents a different NC or NCs


Noncompliance (NC)

- PHIS tracks and counts each regulation verified and each regulation that is noncompliant
- FSIS believes that individual instances of regulatory noncompliance is a better way to measure an establishment's performance than numbers of procedures performed or NRs issued.

NR Number: LIC4709025117N Noncompliance #: 1 Noncompliance status: Open
Regulations Found Noncompliant:

- 416.4(a): Food contact surface, cleaning & sanitizing as frequency
- 416.12(a): develop written procedures
- 416.12(b): plan signed and dated
- 416.12(c): plan identifies procedures for pre-op
- 416.12(d): plan list frequency for each procedure & responsible individual
- 416.13(a): conduct pre-op procedures
- 416.13(c): plant monitors implementation of SSOP procedures
- 416.14: Evaluate effectiveness of SSOP's & maintain plan
- 416.16(a): daily records required, responsible individual, initialed and dated
- 416.16(c): location and retention of records maintained

Noncompliance Description:



At approximately 6:45 am while performing pre-operational sanitation inspection, I observed meat scraps and fat on the mixing arms of the blender in the formulation area. I applied a U.S. Reject tag to the blender. I notified the sanitation manager, Ms. Smith of my findings. After sanitary conditions were restored, I relinquished control of the blender.











The Noncompliance Record (NR)

- Serves as official notice of regulatory noncompliance
- The NR form:
 - Minor changes from PBIS
 - Captures more information
 - Different numbering method

Noncompliance Records

Holland Point Foods

M38572+P38572

NR Number	Task Name	NR Status	Date	Appeal Status	Edit	Delete	Print
LIC4814035930N	Fully Cooked Not Shelf Stable HACCP Verification	Open	3/30/2011	Not under appeal			
LIC0409034131N	Heat Treated Not Fully cooked Not Shelf Stable HACCP	Completed	3/31/2011	Appealed by Plant			
LIC4509030231N	Fully Cooked Not Shelf Stable HACCP Verification	Open	3/31/2011	Not under appeal			
LIC4709025117N	Pre-Operational SSOP Review and Observation	Open	2/17/2011	Not under appeal			
LIC2517043419N	Fully Cooked Not Shelf Stable HACCP Verification	Open	4/19/2011	Not under appeal			
LIC0411015601N	Fully Cooked Not Shelf Stable HACCP Verification	Completed	1/3/2011	Not under appeal			
LIC1412024802N	Fully Cooked Not Shelf Stable HACCP Verification	Completed	2/2/2011	Not under appeal			



Example Noncompliance Record (NR)

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9CFR 301 and 9CFR 381; FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington DC 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

US Department of Agriculture
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
 Food Safety Other Consumer Protection

1. DATE: **2/17/11** 2. RECORD NO.: **LIC4709025117N** 3. ESTABLISHMENT NO.: **M38572**

4. TO (Name and Title): **Mike Adams** 5. PERSONNEL NOTIFIED: **Beth Smith**

6. RELEVANT REGULATIONS: **416.4(a)-Food contact surface cleaning
416.13(c) Plant monitors implementation
of SSOP procedures**

6a. LINKED NR(s)

7. TITLE(S) OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION

7a. NAME OF HACCP CCP(S) or PREREQUISITE PROGRAM

8. INSPECTION TASK: **Pre-Operational SSOP**

9. VERIFICATION ACTIVITY:
 Review & Observation Record Keeping Both

9a. AFFECTED PRODUCT INFORMATION

9b. RETAIN/REJECT TAGS: **B00000057**

Example Noncompliance Record (NR)

10. DESCRIPTION OF NONCOMPLIANCE

At approximately 6:45 am while performing pre-operational sanitation inspection, I observed meat scraps and fat on the mixing arms of the blender in the formulation area. I applied a U.S. Reject tag to the blender. I notified the sanitation manager, Ms. Smith, of my findings. After sanitary conditions were restored, I relinquished control of the blender.

12. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

13. APPEAL STATUS: **Not under appeal**

14. PLANT MANAGEMENT RESPONSE (Immediate action(s)):

15. PLANT MANAGEMENT RESPONSE (further planned action(s)):

This document serves as written notification that your failure to comply with regulatory requirements(s) could result in additional regulatory or administrative action.

16. SIGNATURE OF PLANT MANAGEMENT

17. DATE

18. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

19. DATE

- May be used to document conditions or observations that do not rise to the level of NC, but still need to be discussed with plant management, e.g.:
 - Less than perfect sanitary conditions that could lead to NC if conditions worsen
 - Less than perfect implementation of a prerequisite program

Inspector Note List

Holland Point Foods
M38572+P38572

Create Date	Inspector	Shift	Comments	Category	Edit	Delete
1/1/2011	Robert Barclay	1	Establishment has made a change in the formulation ...	Processing		
1/1/2011	Robert Barclay	1	Noticed that the Sanitation SOP has been signed an ...	Sanitation		
1/1/2011	Robert Barclay	1	Three times this week one of the hand wash sink on ...	Sanitation		
1/1/2011	Robert Barclay	1	Establishment didn't perform an internal temperatu ...	Safety		

Create Note

IPP Communication with Plant Management •

- Entrance meetings
- Awareness meetings
- Weekly meetings
- For cause meetings (e.g., *positive pathogen sample result*)

Weekly Meetings/Agenda Items

- When and Why (Directive 5000.1)
- Possible Topics (Directive 5010.1)
 - In-plant observations
 - Agency issuances
 - FSIS sampling information
 - Information related to the establishment's food safety system
 - Information from external sources
 - Any inspection-related activities occurring outside of approved hours of operation
 - Issues/information establishment wishes to share

Meeting Agenda Tool

Agenda List

Holland Point Foods
M38572+P38572

Subject	Meeting Date	MOI Status	MOI	Edit Agenda	Delete	Report
Presumptive E. coli O157:H7 Positive Sample Result	4/19/2011	Open				
Establishment Awareness Meeting Agenda	3/31/2011	Open				
Establishment NR Meeting	2/2/2011	Finalized				
Establishment Awareness Meeting Agenda	1/9/2011	Finalized				
Entrance Meeting Agenda	1/5/2011	Finalized				

Create Agenda

Weekly Meetings – Dir 5000.1 and 5010.1 •

- Documented in PHIS using the “meeting with establishment management” task
- Meeting notes are documented in an MOI
- IIC responsibilities in multi inspector / multi shift establishments
 - Ensure regulatory concerns from all shifts are discussed
 - May include CSIs and FIs at the meeting
 - May delegate conducting the meeting to IPP

Memorandum of Interview (MOI)

- Purpose
- Document no participation/no response
- No standardized MOI format
- MOI copy is given to the plant

- If an establishment disagrees with any part
 - Establishment should discuss first with IPP
 - IPP will note it at the end of MOI or as attachment
 - Establishment can submit own minutes or notes as attachment
 - Establishment can challenge the MOI following the OFO chain of command

MOIs

MOI List

Holland Point Foods
M38572+P38572

[Add MOI](#) [Add Food Defense OFO](#) [Add Food Defense OIA](#)



Date	Inspector	MOI Number	Type	Status	Edit	Delete	Print
04/19/2011	Robert Barclay	LIC2313043119E	Establishment Meeting MOI	Open			
03/31/2011	Robert Barclay	LIC1610033831E	Establishment Meeting MOI	Open			
02/07/2011	Robert Barclay	LIC3012020007G	MOI	Finalized			
02/02/2011	Robert Barclay	LIC2212021302E	Establishment Meeting MOI	Finalized			
01/13/2011	Robert Barclay	LIC3311010801G	MOI	Open			
01/09/2011	Robert Barclay	LIC3211012301E	Establishment Meeting MOI	Finalized			
01/05/2011	Robert Barclay	LIC3211015101E	Establishment Meeting MOI	Finalized			

Example MOI



United States
Department of
Agriculture

Food Safety and
Inspection Service

Washington, D. C.
20250

To: Mike Adams
Fred Kramer

From: Robert Barclay

Date: 4/19/2011

Meeting Start Time: 9:00 AM

FSA:

Open NRs: LIC4814035930N
LIC4509030231N
LIC4709025117N
LIC2517043419N

NRs Under Appeal: LIC0409034131N

Subject: Presumptive E. coli O157:H7 sample result

Example MOI

1. E. coli O157:H7 Presumptive Positive Result

I notified Mr. Adams and Mr. Kramer 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. 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 Mr. Craig to identify the additional product lots that were produced using the same lot of beef trimmings. Mr. 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. Mr. 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. Kramer and Mr. Craig that if the sample is confirmed positive for E. coli O157:H7, the establishment has shipped adulterated product in commerce because they failed to hold the affected product until FSIS sample results were received. FSIS

- Use Web but need *eAuthentication* account to log into PHIS
- Need at least one PHIS Administrator role
- Access to information in PHIS is based on a user role
- May respond to NRs in PHIS
- May appeal NCs/NRs in PHIS

Plant Management Response to NC/NR

Noncompliance Records

Holland Point Foods
 M38572+P38572

NR Number	Task Name	NR Status	Date	Appeal Status	Edit	Delete	Print
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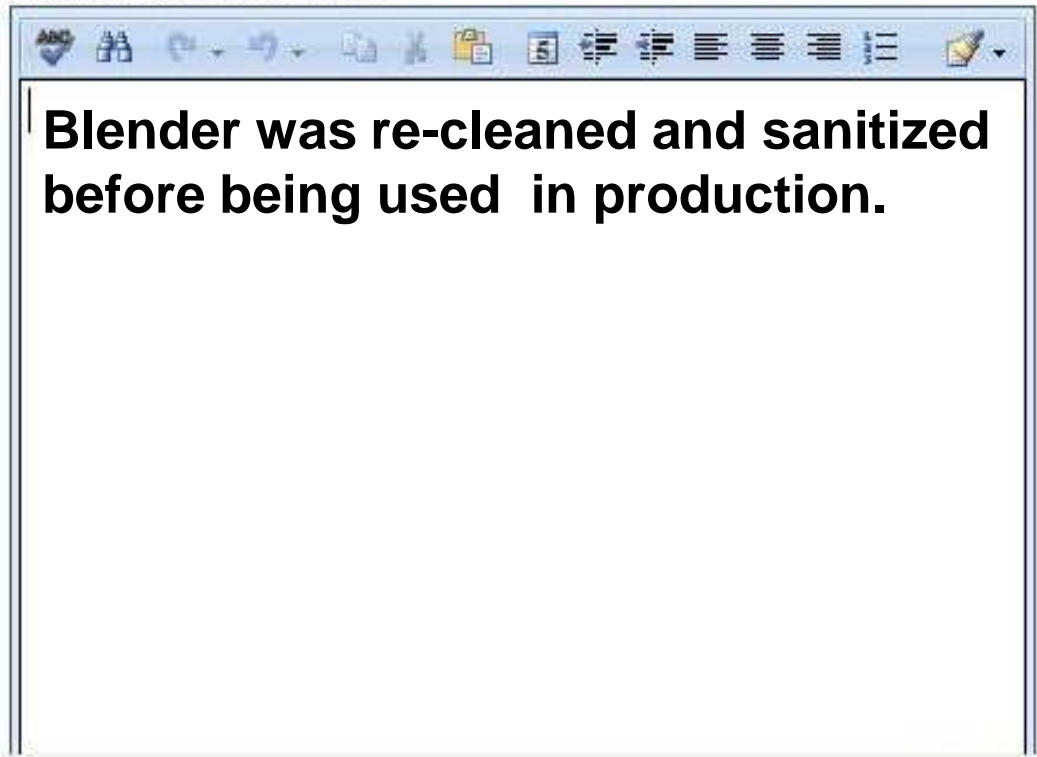
Plant Management Response to NC/NR

Noncompliance Record (NR)

Holland Point Foods
M38572+P38572

General Noncompliances **Response**

Plant Management Response









Blender was re-cleaned and sanitized before being used in production.

Plant Management Response--NC/NR Appeals

Plant Management

Holland Point Foods
M38572+P38572

NR Number	Date	Inspector Name	Under Appeal	View	Response
LIC0409034131N	3/31/2011	Robert Barclay	Yes		 ←
LIC0411015601N	1/3/2011	Robert Barclay	No		
LIC1412024802N	2/2/2011	Robert Barclay	No		

Plant Management Response--NC/NR Appeals

Plant Management Response

Holland Point Foods
M38572+P38572


Appeal

Plant Management Response

NR Number: LIC1412024802N

Name: Role:

Accept FSIS's decision Appeal



Section 416.15 and 416.16 requires us to establish and record preventive measures when product is directly contaminated. Since no product was present during pre-operational sanitation inspection, no product was directly contaminated due to the product residue on the food contact surface.

FSIS Response to Plant NC/NR Appeals

Plant Management Response


Holland Point Foods
M38572+P38572

Appeal

FSIS Response

Grant Deny

NR Number: LIC1412024802N



The establishment restored sanitary conditions before using the blender, and therefore met the requirements of 416.15. Preventive measures are only required when product is directly contaminated or adulterated.

Appeal History is Tracked in PHIS

Holland Point Foods
 M38572+P38572

Appeal

Appeal History			
Action	Reason for Appeal	Reason for Decision	Submitted By
Appealed	Section 416.15 and 416.16 requires us to establish and record preventive measures when product is directly contaminated. Since no product was present during pre-operational sanitation inspection, no product was directly contaminated due to the product residue on the food contact surface.		
Approved		The establishment restored sanitary conditions before using the blender, and therefore met the requirements of 416.15. Preventive measures are only required when product is directly contaminated or adulterated.	Robert LEE Barclay

Questions & Answers

