Wagner, Scott - FSIS

From: Southard, Cindy - FSIS
Sent: Tuesday, April 17, 2012 8:16 AM
To: Doyle, Tom - FSIS
Cc: Nelson, Ron - FSIS; Wagner, Scott - FSIS; Gallegos, Anna - FSIS; Reeder, Robert - FSIS
Subject: FW: FSA

Good Morning Tom,

Thanks for your message. The FSA report for Pecos Valley, establishment 07299, is submitted per your request.


A New 5100-1[1].doc


B GENERAL SANITATION[1].doc


C HACCP 03J Slaughter Meat[1]...


G HACCP 03C Raw Not Ground Mea...

Regards,

Cindy Southard
Supervisory EIAO
Denver District Office
Phone: 303 236-9823
Fax: 303 236 9794
Blackberry: 303 549 8417

From: Doyle, Tom - FSIS
Sent: Tuesday, April 17, 2012 7:58 AM
To: Southard, Cindy - FSIS
Cc: Nelson, Ron - FSIS; Wagner, Scott - FSIS; Gallegos, Anna - FSIS; Reeder, Robert - FSIS
Subject: FW: FSA

Cindy – can you please get me a copy of the FSA request below. It is from Gurinder Saini Brach Chief in ODIFP, and it is a FOIA request thus it is time sensitive.

Tom Doyle- Data Analyst
FSIS/Office of Data Integration
and Food Protection / DAIG
Field Office Analysis Branch
1100 Commerce St. Suite 516
Dallas, TX 75242
Phone: 214-767-1269

From: Saini, Gurinder - FSIS
Sent: Tuesday, April 17, 2012 8:06 AM
To: Doyle, Tom - FSIS
Subject: FSA

Hi Tom:
Please pull out the recent FSA for Establishment M7299, Valley Meat Company, 3845 Cedarvale Road, Roswell, NM. Please send the same to me ASAP.

Thanks

Gurinder Saini (Ph.D, PMP)
Chief - Applied Analysis Branch
USDA, FSIS, ODIFP, 355 E Street.
PP3, Room Number 9-144
Washington, D.C. 20250-3793
202-690-0896
BB 202-257-8011
Gurinder.Saini@fsis.usda.gov

5100-1 (Formerly 5000-8) "Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety System

ESTABLISHMENT AND FSA RESULTS INFORMATION

Establishment Number 07299

Establishment Size: L/S/VS Very Small

FSA Start Date August 9, 2010
FSA End Date October 1, 2010

Name and Address of Establishment
Pecos Valley Meats
3845 Cedarvale Road
Roswell, New Mexico 88203
Phone: 575-622-1214
Email: sada012162@yahoo.com

Parent Corporation (if not privately owned and operated)

Name of EIAO [redacted] and [redacted]

District Denver/15

Circuit Albuquerque/13

Reason for visit (may be able to select more then one):
____FSIS *Lm* Positive Product Sample
____FSIS *Lm* Positive FCS Sample
____FSIS *E. coli* O157:H7 Positive Sample
____FSIS *Salmonella* spp. Positive Sample in RTE Product
____Repetitive Establishment Testing *Lm* Product Positives
____Repetitive Establishment Testing *Lm* FCS Positives
____Repetitive Establishment *E. coli* O157:H7 Positives
____STEPS Database Triggered
____*Salmonella* Set Failure
____Repetitive *Salmonella* positive serotypes of human health concern
____*Salmonella* PFGE matches
____SRM Failures
____Multiple Residue Violations
____Foodborne Illness/Outbreak Investigation
____Foreign Particle Contamination.
____Consumer Complaint
__X__Repetitive NRs of public health concern
____New Establishment
____Documented Change in Process that may impact Public Health
__X__Satisfy 4 year assessment cycle
____RLm Sampling

(to be completed before FSA begins)

The PBIS results of tasks for the period of February 2, 2010, through August 2, 2010, revealed: Scheduled tasks 537, unscheduled tasks 199, total performed tasks 534=62.38%, and total tasks not performed 202=37.62%, tasks with no feed back and non-compliant tasks 11=2.06%.
The grant of inspection was issued on December 19, 1994.

List NRs and other enforcement actions written during the last 6 months:
(If you have 10 or more NRs for the same regulation then you can summarize them)

A review of PBIS showed the following NRs were written during the past 6 months. NR 03-2010, dated on February 16, 2010. This NR was written under the O6D01 procedure for five (5) dead cows were observed on the east side of the property. Mild bloating was observed in the five animals. The establishment has proffered that all dead animals will be removed within the day the animals are either found dead or euthanized by the establishment or USDA PHV. This NR has been closed.

NR 04-2010, dated on February 25, 2010. This NR was written under the O3J02 procedure for no entry indicating the time the event occurred was documented on the establishment's Antimicrobial Intervention Monitoring Log [redacted]) for monitoring CCP-2 of the HACCP Slaughter Plan. This NR has been closed.

NR 05-2010, dated on February 25, 2010. This NR was written under the O3C02 procedure for the establishment failed to meet the sampling frequency as it is stated in its HACCP Raw Not Ground Plan, which states that the [redacted]. This NR has been closed.

NR 06-2010, dated on March 5, 2010. This NR was written under the O6D01 procedure for two (2) dead Jersey dairy cow carcasses on the side of the property. One dairy cow had been found dead and condemned on March 3, 2010, while the other dairy cow had been found dead and condemned on March 4, 2010. The establishment has proffered that all dead animals will be removed within the day the animals are either found dead or euthanized by the establishment or USDA PHV. This NR has been closed.

NR 07-2010, dated April 5, 2010. This NR was written under the O3J02 procedure for the establishment had entered the temperature of the water where the sprayer with [redacted] is kept instead of the temperature of the solution ([redacted] as is documented in the establishment's HACCP Slaughter Plan for CCP 2, which states "[redacted]. The establishment is also not identifying corrective action to be followed in response to a deviation from the critical limit of the [redacted] temperature in its HACCP Slaughter Plan for CCP 2. This NR has been closed.

NR 08-2010, dated on April 16, 2010. This NR was written under the O3J01 procedure for the establishment did not perform the records review verification procedure for records produced on April 15, 2010. The establishment's HACCP plan states, "[redacted]". This noncompliance triggered a O3J02 procedure, in which the five regulatory requirements on records produced on April 15, 2010 were verified. The establishment did not perform the monitoring procedures at the frequencies specified in the HACCP plan for CCP 2, which states "[redacted]". This NR has been closed.

NR 09-2010, dated on April 27, 2010. This NR was written under the O6D01 procedure for five (5) dead dairy cow carcasses were observed on the east side of the establishment and mild bloating was observed in the five animals. These cows had been condemned by the Public Health Veterinarian on April 22, 2010 and were not picked up by the dead stock hauler company the day they were condemned. The establishment has proffered that all dead animals will be removed within the day the animals are either found dead or euthanized by the establishment or USDA PHV. This NR has been closed.

NR 10-2010, dated on April 27, 2010. This NR was written under the O3C02 procedure for a deviation of the critical limit for CCP 4B [redacted]) was found. The temperature of the product taken at 1100 hours was 45° F and the temperature of the product taken at 1245 hours was 47° F. Both temperatures taken did not meet the critical limits. The establishment's Raw Not Ground HACCP Plan specifies that the critical limit for raw product temperature is [redacted] and no corrective actions were documented. This NR has been closed.

NR 11-2010, dated on May 11, 2010. This NR was written under the O6D01 procedure for the overhead roll-up door in the inedible cooler that opens to the outside has gaps around the jambs and at the bottom part due to the fact that the door does not close tightly. On the downer ramp, next to the knocking area there were three old tires, scrap metal, old rusty fans, two rusty chains stored on the floor, and a 50 gallon plastic barrel full of trash being stored in this area. This NR has been closed.

NR 12-2010, dated on June 1, 2010. This NR was written under the O6D01 procedure for the establishment did not have the documentation to support the safety of chemicals used in the food processing environment. The establishment did not have the documentation for the following chemicals [redacted] This NR has been closed.

NR 13-2010, dated on July 22, 2010. This NR was written under the O5A02 procedure for the establishment did not conduct Generic *E. coli* testing as per 9 CFR 310.25 (a), which requires that each official establishment that slaughters livestock must test for *Escherichia coli* Biotype 1. Also the establishment must test per the criteria set forth in 9 CFR 310.25 (a)(2)(v)(A) and the establishment must maintain records that document analytic results in accordance with 9 CFR 310.25 (a)(4). This NR has been closed.

Two Free Text boxes for EIAO analysis addressing the following statements:

- Briefly discuss any preliminary food safety system implementation and/or design issues demonstrated by the NRs listed above.

A review of the previous NRs from February 1, 2010 through August 1, 2010, revealed the establishment had a total of 11 documented noncompliance reports (NRs). Three (3) O6D01 NRs have been written over the last 6 months that were linked with one another. NR 3-2010 and NR 6-2010, dated February 16, 2010 and March 5, 2010, were linked to NR 35-2009, dated December 18, 2009, for insanitary conditions observed outside of the premises. NR 9-2010, dated April 27, 2010, was linked to NR 6-2010, dated March 5, 2010, for insanitary conditions observed outside the premises as well. These three (3) O6D01 NRs show that the establishment's further planned actions are ineffective in preventing the noncompliance from recurring. The establishment also had one (1) O3J02 NR that was linked with a O3J01 NR over the last 6 months. NR 8-2010, dated April 16, 2010, was linked to NR 7-2010, dated April 5, 2010, for the establishment was not performing monitoring and records review verification procedures at the frequencies specified in the HACCP Plan. The establishment also had one (1) O3J02 NR that was linked with a O3C02 NR over the last 6 months. NR 10-2010, dated April 27, 2010, was linked to NR 4-2010, dated February 25, 2010, for the establishment was not indicating the time the

event occurred on the monitoring log records and the establishment did not document the corrective actions, including all actions taken in response to a deviation. These two (2) NRs show that the establishment's further planned actions are ineffective in preventing the noncompliance from recurring.

- Briefly discuss how the above identified food safety implementation and/or design issues impact public health and the establishment's ability to produce unadulterated product.

The documented noncompliances by the in-plant inspection team document implementation and design issues with the written HACCP and SSOP programs. These documented noncompliances reviewed from February 1, 2010 through August 1, 2010, do not negatively impact the food safety system.

Describe the available FSIS sampling result history:
(Please include any sampling done as part of the FSA as results are available)

3/16/2010 – Sample # 11413836; *E. coli* O157:H7 - negative

Completed Salmonella Sets- completion date 2/27/2010; sample set #4; Category-3; total samples-58, positive samples-3; results- fail

3/19/2010 – Sample # 00505353; Residue – not detected
3/30/2010 – Sample #00504796; Residue – not detected
3/31/2010 – Sample #00504797; Residue – not detected
4/1/2010 – Sample #00504798; Residue – not detected
4/6/2010 – Sample #00504799; Residue detected – non-violative
4/20/2010 – Sample #00504800; Residue detected – violative
4/20/2010 – Sample #50180659; Residue – not detected
5/20/2010 – Sample # 00504702; Residue detected – violative
5/21/2010 – Sample # 00504703; Residue – not detected
6/3/2010 – Sample # 00504704; Residue – not detected

Two Free Text boxes for EIAO analysis addressing the following statements:

- Briefly discuss any preliminary food safety system implementation and/or design issues demonstrated by any positive samples listed above.

A review of the results from the completed Salmonella Sets reveals food safety concerns or issues with the design and implementation of the establishment's food safety system since the establishment failed sample set # 4. The reported violative residue results indicate that the establishment may not have taken adequate measures to ensure animals are drug residue free at the time of receiving.

- Briefly discuss how the above identified food safety implementation and/or design issues impact public health and the establishment's ability to produce unadulterated product.

A review of the results from the completed *Salmonella* Sets indicates there is an impact on the establishment's food safety system. The results of the violative residue indicate that the establishment's pre-requisite program (Drug Residue Policy Program) is being followed as written. An analysis of the program and associated records reveals the establishment has taken adequate measures to ensure animals are drug-residue free at the time of receiving.

Pecos Valley Meats, Est. 07299, 5100-1

Has the plant had a consumer complaint in the last 6 months? No

Free text box for EIAO analysis addressing the following statement:

- Describe any consumer complaints found over the last 6 months.

A search of CCMS II revealed no consumer complaints in the past 6 months.

What HACCP Categories does the plant utilize? Check all that apply: Answer all sections where a check is applied. All FSAs should have a completed General Sanitation section.

03B Raw Ground

[redacted]

03C Raw, Not Ground

[redacted]

_____03D Thermally Processed/Commercially Sterile

03E Not Heat Treated Shelf Stable

[redacted]

03F Heat Treated Shelf Stable

[redacted]

03G Fully Cooked-Not Shelf Stable

[redacted]

03I Secondary Inhibitors, Not Shelf Stable

[redacted]

03J Slaughter

[redacted]

Is the plant under Dual Jurisdiction inspection? No If yes, complete Dual Jurisdiction section.

Does the plant have a written Food Defense plan? No If yes, complete Food Defense section.

Free text Box: Describe the Entrance Conference.

On August 9, 2010, at 1100 hours, Enforcement Investigative Analysis Officers (EIAOs) [redacted] and [redacted] held an entrance meeting with Mr. [redacted] Supervisory Public Health Veterinarian (SPHV) and Mr. [redacted] Consumer Safety Inspector (CSI). Front Line Supervisor, Dr. [redacted] was unavailable to attend the Entrance Meeting. EIAO [redacted] discussed the purpose of the comprehensive food safety assessment of the establishment's entire food safety system. EIAO [redacted] explained the purpose of the assessment and what assistance would be required from FSIS staff and that the FSIS staff will be informed of all findings as the assessment progressed. EIAO [redacted] advised SPHV [redacted] and CSI [redacted] of the possible results of the FSA and that she would try to answer any questions that they may have about the process as they came up. SPHV [redacted] and CSI [redacted] were also informed that if there were any questions during the performance of the FSA, they would be answered during the assessment process.

On August 9, 2010, at 1130 hours, EIAO [redacted] and [redacted] held an entrance meeting with Mr. Rick De Los Santos, Plant Owner and Ms. Sarah De Los Santos, to explain the purpose of the Assessment. Mr. [redacted] and Mr. [redacted] were also present. EIAO [redacted] explained that the purpose of the assessment was to assess the firm's entire food safety system and informed Mr. and Ms. De Los Santos of the documents needed (HACCP and SSOP plans, pre-requisite programs, records, supporting documentation for decision-making etc). EIAO [redacted] informed Mr. and Ms. De Los Santos that the assessment would be conducted in a manner to be as stress free as possible and that EIAO [redacted] would understand if the plant management had to leave from time to time to conduct company business. EIAO [redacted] advised that the in-plant inspection team was responsible for the daily regulatory oversight at the establishment. It was further explained the possible results of the assessment could be: No further action, 30 day letter, Notice of Intended Enforcement (NOIE), suspension/withdrawal or Non-Compliance Reports (NRs) issued. EIAO [redacted] explained that Comprehensive Food Safety Assessments will be conducted every four years and the four year Comprehensive Food Safety Assessment cycle started in August 2009. Mr. and Ms. De Los Santos were asked if he or she had any questions that could be answered at this time. EIAO [redacted] answered all questions plant management had at that time.

Free Text Box: Describe the Exit Conference

[redacted] and I held an exit conference on October 1, 2010, at 0930 hours via teleconference, with Supervisory Public Health Veterinarians (SPHVs) [redacted] and [redacted] and Consumer Safety Inspector (CSI) [redacted] following the completion of the food safety assessment. Front Line Supervisor [redacted] was unable to attend the Exit Meeting. Acknowledgement was presented for the cooperation that was received from the in-house inspection team during the assessment. EIAO [redacted] asked Supervisory Public Health Veterinarians (SPHVs) [redacted] and [redacted] and Consumer Safety Inspector (CSI) if they had any questions with the noncompliance's that were found during the Food Safety Assessment. EIAO [redacted] informed Supervisory Public Health Veterinarians (SPHVs) [redacted] and [redacted] and Consumer Safety Inspector (CSI) [redacted] of the recommendations and answered their questions and informed them that they would receive a copy of the assessment via e-mail along with associate documents if any.

Pecos Valley Meats, Est. 07299, 5100-1

[redacted] and I held an exit conference on October 1, 2010, at 1000 hours with Mr. and Mrs. Rick De Los Santos, Plant Owners. Also in attendance were Supervisory Public Health Veterinarians (SPHVs) [redacted] and [redacted] and Consumer Safety Inspector (CSI) [redacted] following the completion of the food safety assessment. EIAO [redacted] reviewed all findings, answered their questions and discussed the recommendation. EIAOs [redacted] and [redacted] presented Mr. De Los Santos and inspection personnel with a draft copy of the assessment at the exit meeting. EIAOs [redacted] and [redacted] informed Mr. and Mrs. De Los Santos that the District Case Specialist would either email or Fed-ex a copy of the final version of the Food Safety Assessment to them. EIAOs [redacted] and [redacted] thanked Mr. and Mrs. De Los Santos for the firm's willingness and cooperation throughout the assessment.

Free Text Box: List any Reference Source Materials given to the plant during the FSA
NONE

GENERAL SANITATION: SPS and SSOP

(To be answered for all FSAs)

GS1. Is the building maintained in a sound condition as described in 9 CFR 416 (e.g., no leaks, wall integrity good, no standing water)? No

GS1a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

On August 9, 2010, Mr. Rick De Los Santos, Plant Owner, conducted a walk through of the establishment with Enforcement Investigations Analysis Officers (EIAOs) Ms. [redacted] and Ms. [redacted]. Mr. De Los Santos showed EIAOs [redacted] and [redacted] the overall slaughter and fabrication processes as well as the storage areas of the plant.

EIAOs [redacted] and [redacted] observed the establishment's ceilings, walls, and doors to be in good condition, built of durable materials and impervious to moisture, except for the following:

- On August 19, 2010, EIAOs [redacted] and [redacted] observed a slow water drip from a juncture in the ceiling beam that was located in the center of the carcass cooler by the north east wall. The water was dripping close to a grey combo bin that had four (4) boxes of sample cuts of meat. EIAOs [redacted] and [redacted] observed no boxes of product with water on them. EIAOs [redacted] and [redacted] informed Dr. [redacted], Public Health Veterinarian and Mr. Rick De Los Santos, Plant Owner of the noncompliance. Mr. De Los Santos took immediate corrective action and moved the grey combo bin out of the area. Dr. [redacted] informed CSI [redacted] of the noncompliance and CSI [redacted] issued the establishment a noncompliance report (NR 16-2010, dated August 19, 2010). This is a noncompliance with 9 CFR 416.2 (d) and 416.4 (d).

- On August 17, 2010, EIAOs [redacted] and [redacted] observed the covering on the baseboard on the north wall of the slaughter floor that was approximately three (3) feet long on both the left and right sides of the swinging double doors by the splitting saw and stand is loose and coming off the wall. This is a noncompliance with 9 CFR 416.2 (b)(1).

The floors in the slaughter and fabrication rooms are cement and the floor in the employee restroom is concrete and in the office restroom is tile. The floors in the front offices are tiled. The dry and cold storage areas of the establishment are cement and in good condition. The walls in the slaughter floor and the raw processing room are fiber glass board and are in good condition. The walls in the offices, dry and cold storage areas, and restrooms are painted dry wall and are in good condition. The establishment has hot and cold running water in the restrooms and on the slaughter floor and in the raw processing room. Each sink on the slaughter floor and in the raw processing room and in the restrooms are equipped with soap and paper towel dispensers. The floor drains were functioning as intended to provide adequate drainage of water during processing and cleaning operations.

The airflow throughout the slaughter floor was adequate as no condensation, vapors, or obnoxious smells were observed during the course of the assessment, except for the following:

- On August 19, 2010, EIAOs [redacted] and [redacted] observed beaded condensate on the ceiling in the raw processing room right above the freezer doors. EIAOs [redacted] and [redacted] observed no condensate dripping at the time. EIAOs [redacted] and [redacted] informed Mr. [redacted], Boning Room Employee, of the

noncompliance. Mr. [redacted] took immediate corrective action by wiping down the condensation. EIAOs [redacted] and [redacted] discussed noncompliance with CSI [redacted] CSI [redacted] informed EIAOs [redacted] and [redacted] that he had previously written a noncompliance report for condensation on the bottom of the cooling unit (NR 14-2010, dated August 9, 2010). Mr. [redacted] issued the establishment a noncompliance report (NR 16-2010, dated August 19, 2010). This is a noncompliance with 9 CFR 416.2 (d).

The level of lighting was adequate to observe the slaughter and raw processes in the different areas of the slaughter and processing room. All lighting on the slaughter floor and in the raw processing room was observed to be adequately sealed for food safety and to protect against accidental breakage.

GS2. When was the main "brick and mortar" structure of the premises built?

__Before 1960
__1960-1970
__1970-1980
_X_1980-1990 – 1983, is when the main structure of the premises was built.
__1990-2000
_X_2000-Present – 2005, is when the establishment expanded the building to add coolers to the facility.

GS3. Is the equipment free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures? Yes

GS3a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

On August 11, 2010, EIAOs [redacted] and [redacted] observed Mr. [redacted], Kill Floor QC perform pre-operational sanitation by inspecting each area on the Kill Floor. Mr. [redacted] inspected all areas such as the head wash station/[redacted], gutters drop/gut buggy, splitting saw, and edible offal rack. Mr. [redacted] also recorded the temperatures of the sterilizers. EIAOs [redacted] and [redacted] observed the equipment to be free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures.

On August 11, 2010, EIAOs [redacted] and [redacted] observed Mr. [redacted], Processing Room QC perform pre-operational sanitation by inspecting the sales cooler, tops and bottoms of tables, record the sterilizer temperature, and inspect the walls and floors in the processing room. Mr. [redacted] also checked the hand wash sink to make sure there were paper towels and soap. In addition, Mr. [redacted] monitored the temperature of the processing room and freezer. EIAOs [redacted] and [redacted] observed the equipment to be free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures.

GS4. Are there any findings during the course of the FSA that raise a concern as to whether the sanitation system is adequate to meet the sanitation performance standard requirements (e.g. ventilation, condensation, structural integrity)? No

(Question GS4 refers to all of the Sanitation Performance Standards, covered under 416.1-416.4)

GS4a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. Briefly describe your observations and any non-compliance with the SPS regulations.

Overall the sanitation system is adequate to meet the sanitation performance standards, except for the noncompliance's noted above in GS1a.

Pecos Valley Meats, Est. 07299, General Sanitation: SPS and SSOP

Pecos Valley Meats consists of one building that is [redacted]. Pecos Valley Meats is classified as a very small establishment with approximately ten (10) employees, which includes slaughter, processing and management employees. Pecos Valley Meats has a slaughter floor and a raw not ground processing room. Pecos Valley Meats produces USDA inspected and Custom Exempt products.

Pecos Valley Meats is located off of Cedarvale Road in Roswell, New Mexico. The outside premises of the establishment has [redacted].

Pecos Valley Meats controls the harborage of pests at its facility. Pecos Valley Meats has contracted [redacted], which is located in Roswell, New Mexico to handle monthly pest control service including rodent bait boxes and bug spraying. The establishment has seven (7) bait boxes that surround the establishment and are located at entrances into the establishment. An assigned plant employee will spray plant perimeter for flies at least two (2) times per day or as needed to control flies during the fly season. Maintenance employee will be responsible for deciding how often or when to spray. During the fall and cooler months spraying will be done as needed to control flies. In the event that flies are noticed on the slaughter floor, the foreman will shut down the slaughter process, process all carcasses/move them into hot box, fog slaughter floor, rinse all areas and will resume slaughter. This process will be done as often as needed during fly season. If a fly is found on a carcass, the carcass will be re-trimmed, re-inspected and sprayed with anti-microbial spray. Slaughter floor foreman will monitor for flies and take necessary action to prevent product contamination. Livestock pens will be washed as needed to control flies, dirt pens will be cleaned once per week or more often if needed. The establishment has three (3) fly bait boxes that are located around the pen.

EIAOs [redacted] and [redacted] reviewed the "Outside Premise Fly Spraying and Fogging Log" records from June 13, 2010 through August 9, 2010, to include the power fogging, spraying, and filling of bait boxes by [redacted]. EIAOs [redacted] and [redacted] observed that the establishment monitored, at the frequencies, for flies as stated in the Fly and Pest Control Program.

Pecos Valley Meats is connected to the City of Roswell, New Mexico public water system. Pecos Valley Meats provided a copy of the most recent water certificate by the City of Roswell for the community system. The City of Roswell checks the water system three (3) times per year per location. The most recent certificate, dated July 8, 2010, indicated that the location tested was on 6003 South Graves Road Station number 5, which is closest to the establishment's physical location. The results showed that there was 0.7 mg/l of total Cl_2, the absence of total coliforms per 100 ml and the absence of *E. coli* per 100 ml. The establishment does not use ice or reconditioned water. Backflow devices are used in the establishment, but are not tested annually.

Throughout the course of the Food Safety Assessment, EIAOs [redacted] and [redacted] observed the plumbing in the establishment was adequate to supply water throughout the production facility as needed. The plant drainage system in the slaughter and processing areas adequately remove waste water from the slaughter and the production areas as needed. Water is controlled in the facility, no pooling of water was observed during the Food Safety Assessment.

GS5. Are the SSOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product? Yes

Pecos Valley Meats, Est. 07299, General Sanitation: SPS and SSOP

GS5a. Are the sanitation SOPs signed and dated? Yes

GS5b. Are the pre-operational sanitation procedures identified as such? Yes

GS5c. Do the procedures in the Sanitation SOP address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils? Yes

GS5d. Do the Sanitation SOPs specify the frequency with which each procedure in the Sanitation SOPs and do they identify the establishment employee responsible for the implementation and maintenance of such procedures? Yes

GS5e. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. Describe how you came to the conclusion to GS5.

On August 9, 2010, EIAOs [redacted] and [redacted] reviewed the establishment's Sanitation SOPs and observed that the Sanitation SOPs were signed and dated by Mr. Rick De Los Santos, Plant Owner on January 6, 2010. EIAOs [redacted] and [redacted] observed that the Sanitation SOPs specify the frequency with which each procedure in the Sanitation SOPs are being performed. The Sanitation SOP also identifies the establishment employee(s) who are responsible for implementation and daily monitoring of the Sanitation SOP, and recording the findings and any corrective actions as the Kill Floor QC, Processing Room QC, Program Monitor, and the Plant Sanitation Manager.

[redacted]

[redacted]

Room Temperature Controls

[redacted]

GS6. Does the plant have an extended cleanup (less than daily) written in the SSOP? No

GS6a. If yes, does the design of the procedure support extended clean up? N/A

GS6b. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment does not have an extended cleanup (less than daily) written in the SSOP.

GS7. Are all sanitation procedures conducted incorporated into the SSOP? Yes

GS7a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

On August 11, 2010, EIAOs [redacted] and [redacted] observed Mr. [redacted], Kill Floor QC perform pre-operational sanitation by inspecting each area on the Kill Floor. Mr. [redacted] inspected all areas such as the head wash station/[redacted] rod/[redacted] clips, gutters drop/gut buggy, splitting saw, and edible offal rack. Mr. [redacted] also recorded the temperatures of the sterilizers.

On August 11, 2010, EIAOs [redacted] and [redacted] observed Mr. [redacted], Processing Room QC perform pre-operational sanitation by inspecting the sales cooler, tops and bottoms of tables, record the sterilizer temperature, inspect the walls and floors in the processing room. Mr. [redacted] also checked the hand wash sink to make sure there were paper towels and soap. In addition, Mr. [redacted] monitored the temperature of the processing room and freezer.

GS8. Does the plant monitor the implementation of SSOP procedures no less than daily as required under 9 CFR 416.13 (c)? Yes

GS8a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision in GS8.

Pecos Valley Meats, Est. 07299, General Sanitation: SPS and SSOP

The SSOP procedures reflect the performance of pre-operational procedures to be conducted daily before each production day by the Kill Floor QC and the Processing Room QC to prevent direct contamination or adulteration of products. The operational procedures are performed twice per day, once in the morning and once in the afternoon. A review of the "Form KF-1" records and "Daily Operational Procedures-Form KF-2" Dairyland Packing Inc. dba Pecos Valley Meats, Est. 7299 records on August 10, 2010, from May 4, 2010 through August 5, 2010, records confirmed the establishment does monitor and document the implementation of the SSOP program daily. A review of the "Form PR-1" and the "Daily Operational Procedures-Form PR 2" Dairyland Packing Inc. dba Pecos Valley Meats, Est. 7299 records on August 10, 2010, from May 1, 2010 through July 30, 2010, records confirmed the establishment does monitor and document the implementation of the SSOP program daily.

On August 11, 2010, EIAOs [redacted] and [redacted] observed Mr. [redacted], Kill Floor QC and Mr. [redacted], Processing Room QC perform operational sanitation. Mr. [redacted] and Mr. [redacted] inspected Kill Floor stations and the Processing Room to ensure areas were clean, employees were sanitizing knives, and washing their hands. Mr. [redacted] and Mr. [redacted] documented their findings on the "Daily Operational Procedures-Form KF-2" Dairyland Packing Inc. dba Pecos Valley Meats, Est. 7299 record and the "Daily Operational Procedures-Form PR 2" record.

GS9. Has the establishment maintained daily SSOP records as required? Yes

GS9a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the Dairyland Packing, Inc. dba Pecos Valley Meats, Est. 7299 "Form KF-1" records and "Daily Operational Procedures-Form KF-2" Dairyland Packing Inc. dba Pecos Valley Meats, Est. 7299 records on August 10, 2010, from May 4, 2010 through August 5, 2010. EIAOs [redacted] and [redacted] reviewed the Dairyland Packing, Inc. dba Pecos Valley Meats, Est. 7299 "Form PR-1" and the "Daily Operational Procedures-Form PR 2" Dairyland Packing Inc. dba Pecos Valley Meats, Est. 7299 records on August 10, 2010, from May 1, 2010 through July 30, 2010. The establishment's SSOP records were complete and had been documented daily as required. All pre-operational and operational records were filled out and were signed by the person inspecting the area. The "Form KF-1", "Daily Operational Procedures-Form KF-2", "Form PR-1", and "Daily Operational Procedures-Form PR 2" records included the results of all procedures that are included in the SSOP program.

- On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the "Form PR-1" records from May 1, 2010 through July 30, 2010, and observed that the pre-operational sanitation/processing room procedure lists that the [redacted] that will be used as an area to check for pre-operational sanitation, but it is not listed or checked on the "Form PR-1" record. This is a noncompliance with 9 CFR 416.13 (a) (b) (c).

- On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the "Form PR-1" records from May 1, 2010 through July 30, 2010, and observed that there is no sterilizer temperature recorded on the following dates: May 3, 4, 5, 26, and 31, 2010, June 18, 2010, July 9 and 13, 2010. In the pre-operational processing procedure it states, [redacted]". This is a noncompliance with 9 CFR 416.16 (a).

GS10. Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 416.15 (a)? Yes

GS10a. If yes, were all applicable parts of 9 CFR 416.15 (b) met? Yes

GS10b. Why did you come to this conclusion? Briefly describe the corrective actions taken and discuss any noncompliances. Describe the observations and/or documents used to reach your decisions in GS10 and GS10a.

EIAOs [redacted] and [redacted] reviewed "Form KF-1" and "Daily Operational Procedures-Form KF 2" records on August 10, 2010, from May 4, 2010 through August 5, 2010. Upon review of the records, the establishment had taken appropriate corrective actions as required in 9 CFR 416.15.(b) for each of the deficiencies the pre-operational and operational monitor observed during pre-operational and operational monitoring activities.

Upon review of the "Form KF-1" records on May 28, 2010, pieces of fat were observed in the gutters drop/buggy. The designated employee inspecting the area took immediate corrective action and recorded the finding and the corrective actions on the "Form KF-1" under Action Taken. For the corrective actions, the gutters drop/buggy was rewashed and sanitized, was re-inspected, and was found acceptable.

Upon review of the "Form KF-1" records on May 27, 2010, pieces of fat were observed on the carcass wash stand. The designated employee inspecting the area took immediate corrective action and recorded the finding and the corrective actions on the "Form KF-1" under Action Taken. For the corrective actions, the carcass wash stand was rewashed and sanitized, was re-inspected, and was found acceptable.

Upon review of the "Form KF-1" records on May 21, 2010, pieces of fat were observed on the trimmer stand and sterilizer. The designated employee inspecting the area took immediate corrective action and recorded the finding and the corrective action on the "Form KF-1" under Action Taken. For the corrective actions, the trimmer stand and sterilizer was rewashed and sanitized, was re-inspected, and was found acceptable.

GS11. Does the establishment conduct microbiological testing as part of the SSOP? Yes

GS11a. If yes, what organism(s)? Check all that apply

_X_Generic *E. coli*
__Coliform
__*Enterobacteriaceae*
__APC
__ATP luminescence
__Other, please specify (free text box)

GS11b. Is the procedure designed to find the organisms of concern? Yes

GS11c. Does the plant use the data in decision making? Yes

GS11d. Why did you come to these conclusions? Describe the observations and/or documents used to reach your decisions in GS11, GS11a – c.

Pecos Valley Meats employs the [redacted] and [redacted] in Cactus, Texas to conduct the microbiological sample testing. The laboratory utilizes the Validation of the Efficacy of [redacted] Proposed Statement of Work (SOW), procedure MB072, ECC Film method to test for Generic *E.* coli. The objective of an intervention validation study is to determine the effectiveness of application of a chemical sanitizer to a meat surface (carcass, subprimal or trimmings) is effective as a microbial intervention. The establishment will repeat

their validation study in the summer months on a smaller scale with guidance from [redacted] regarding the scope and number of samples needed to adequately continue to validate their process.

The microbiological laboratory analysis for microbial counts at [redacted] and [redacted] in Cactus, Texas are the following: This is the establishment's [redacted] Validation Study and the testing method that the [redacted] and [redacted] are using. Analysis of samples may include the following analyses: total aerobic plate counts (APC), total coliform counts (TCC), and biotype I *E. coli* counts (ECC) will be performed using standard serial dilution and plate counting methods (BAM, 1998). Tenfold serial dilutions prepared in 0.1% peptone water will be plated on petrifilms (3M) and incubated aerobically for 24 hours at 35° C. Petrifilms containing between 30 and 300 colony forming units (CFU) (or the highest number if below 30) will be enumerated and converted in to log CFU to accommodate the anticipated wide fluctuation common to biological data. This study is designed to allow a 0.5 log difference.

On August 12, 2010, EIAOs [redacted] and [redacted] reviewed the establishment's Generic *E. coli* Testing Procedures and observed that the establishment will collect the sample by randomly picking a carcass by using numbered carcasses from previous days slaughter. The testing will be done according to USDA regulations and the establishment will sample 13 consecutive samples. The carcass swabbing will be done in the cooler. The designated employee will wash hands and put on a clean frock before entering the cooler. The sampling supplies will be assembled on clean stainless steel tables and the solution will be poured into the sponge bag. The designated employee will put on sterile gloves. The area to be sampled will be 300 cm^2 and the designated employee will use a template and will sponge the carcass on the flank and brisket with one side of the sponge and the sponge will be turned to the other side to sponge the inside round. The sponge will be put in a twist lock bag and the bag will be put into a zip lock bag with the establishment number, carcass number, date and time of sampling. The zip lock bag will then be put into the cold storage box and shipped to the [redacted] and [redacted] which is located in Cactus, Texas. Sample results are faxed to Pecos Valley Meats as soon as they are analyzed. The results are recorded onto a control chart and kept in the Generic *E. coli* binder.

EIAOs [redacted] and [redacted] reviewed the establishment's Generic *E. coli* testing results and observed that the establishment took Generic *E. coli* samples on July 28, 2010 and August 5, 2010. The results were < 0.08 cfu/sq cm for Generic *E. coli* and were documented on a certificate of analysis from [redacted] and [redacted] and on a control chart.

GS12. Are employee hygiene procedures available in a written document? Yes

GS13. Are employees trained in hygiene procedures? Yes

GS13a. Describe the training procedures, observations and/or documents used to reach your decision and discuss whether they are adequate to prevent direct product contamination. Are they available in multiple languages?

On August 10, 2010, EIAOs [redacted] and [redacted] observed in the establishment's operational sanitation program that employees are instructed to wash hands with soap and water as needed to prevent product contamination. Clean frocks are issued to each employee to prevent product contamination and are changed as needed. Gloves are to be changed as needed. Employees will clean and sanitize personal equipment as needed to prevent product contamination. The training procedures are available in English, but the Plant Owner, Mr. Rick De Los Santos, is fluent in Spanish and English.

The establishment also has an Employee Training Guide where Plant Management and [redacted]

On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the Training/Safety/Sanitation Meeting Report records on May 4, 2010, June 7, 2010, and July 26, 2010, and observed that the document contained the following information: the date, the topics discussed, the names of the employees who attended the training, and the person conducting the training.

On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the Employee Training and Sanitary Dressing Procedures document on April 5, 2010 and June 7, 2010, and observed that the document contained the following information: the date, employee signature/title of position and the HACCP Coordinator signature.

The establishment also has a Humane Handling of Livestock Employee Training and Monitoring Protocol. All new employees will be trained by the Kill Floor Manager or assigned QC. Training will involve humane handling and humane slaughter of all livestock. Knocking area employees will be trained on correct knocking and handling of livestock. All pen and knocking area employees will be required to sign a statement verifying their understanding of protocol. Employees will be disciplined or replaced if necessary.

On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the Humane Handling and Slaughter Employee Training records on July 26, 2010, and observed that the document contained the following information: the date, employee name, the type of training/responsibility, employee signature, department, and management signature.

GS14. Are outer garments removed when leaving work area? Yes

GS15. Are gloves used properly? Yes

GS15a. Describe how you came to the conclusion in GS15.

On August 11, 2010, EIAOs [redacted] and [redacted] observed employees on the Kill Floor remove their aprons when leaving the Kill Floor area before going to the restroom or breakroom. The employees washed their hands upon

returning to the Kill Floor and donned their aprons. EIAOs [redacted] and [redacted] observed employees change their gloves as needed.

GS16. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work? Yes

GS17. Are food and operator hand tools (knives/food contact utensils) stored in a sanitary manner? Yes

GS18. Does the establishment rotate sanitizers? Yes

GS18a. If yes to GS18a, describe the rotation procedure.

Pecos Valley Meats uses [redacted] parts per million (ppm) on food contact surfaces. After every two weeks the establishment will rotate the [redacted] parts per million (ppm) on food contact surfaces as well. EIAOs [redacted] and [redacted] observed the designated employee measure the parts per million (ppm) of the [redacted] on August 13, 2010, and observed the [redacted] parts per million (ppm) as recommended by manufacture's recommendations.

GS18b. Why did you come to these conclusions? Describe the observations and/or documents used to reach the decision. Describe any findings during review of the SSOP records.

The employees use a 20 second hand wash method before starting and returning to work. On August 11, 2010, EIAOs [redacted] and [redacted] observed employees wash their hands with soap and water as they entered into the processing room. The equipment and utensils are constructed of stainless steel that allow for proper cleaning and sanitizing of surfaces. The employees keep their knives and hooks in their scabbards. EIAOs [redacted] and [redacted] observed the establishment is maintaining the equipment and utensils in a sanitary condition.

EIAOs [redacted] and [redacted] observed the designated employee measure the parts per million of the [redacted] on August 13, 2010, and observed the [redacted] parts per million (ppm) as recommended by manufacture's recommendations.

GS19. Describe any sanitation findings not addressed in any of the previous questions.

The establishment has a plant improvement program to do repairs and maintenance on a weekly basis, to prevent insanitary conditions. The establishment lists what items/locations need to be repaired or fixed on a calendar. EIAOs [redacted] and [redacted] reviewed the plant improvement plan and observed that some items need several days to get fixed/repaired and the establishment would put a target date of when the items/locations would be fixed by.

GS20. Analysis and Summary: Briefly describe the SPS/SSOP program design and any concerns and/or non-compliances found by summarizing your analysis of the above gathered data related to your sanitation findings. Also include positive findings.

During the course of the Comprehensive Food Safety Assessment conducted at Pecos Valley Meats, Est. 7299, from August 9, 2010 through August 20, 2010, EIAOs [redacted] and [redacted] observed that the establishment was operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product was not adulterated. The establishment has a SSOP plan that contains procedures that will be conducted daily to prevent direct contamination or adulteration of products. A review of the SSOPs records indicated that procedures were being implemented, maintained, corrective actions taken, and recordkeeping

requirements met. The establishment's SSOP were developed, implemented, and maintained to meet all regulatory requirements, except for the following:

- On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the "Form PR-1" records from May 1, 2010 through July 30, 2010, and observed that the pre-operational sanitation/processing room procedure lists that the [redacted], but it is not listed or checked on the "Form PR-1" record. This is a noncompliance with 9 CFR 416.13 (a) (b) (c).

- On August 10, 2010, EIAOs [redacted] and [redacted] reviewed the "Form PR-1" records from May 1, 2010 through July 30, 2010, and observed that there is [redacted] on the following dates: May 3, 4, 5, 26, and 31, 2010, June 18, 2010, July 9 and 13, 2010. In the pre-operational processing procedure it states, "[redacted]". This is a noncompliance with 9 CFR 416.16 (a).

- On August 17, 2010, EIAOs [redacted] and [redacted] observed the coving on the baseboard on the north wall on the slaughter floor that was approximately three (3) feet long on both the left and right sides of the swinging double doors by the splitting saw and stand is loose and coming off the wall. This is a noncompliance with 9 CFR 416.2 (b)(1).

EIAO [redacted] and [redacted] recommend this deficiency be addressed through the issuance of non-compliance reports written by in-plant inspection personnel.

HACCP 03J Slaughter Meat

Which of the following products does the plant produce under HACCP 03J?

____Pork (answer general, sanitary dressing, interventions and validation, animal drug and biological residues, custom exempt, and miscellaneous questions only)
__X__Beef (answer all questions)
____Other species (answer general, sanitary dressing, interventions and validation, animal drug and biological residues, custom exempt, and miscellaneous questions only)

GENERAL (all species)

G1. List all HACCP 03J plans, products produced using those plans, CCPs, critical limits, monitoring procedures, and verification procedures associated with those plans using the table format provided.

HACCP Plan	Products Produced	CCP	CL	Monitoring Procedures	Verification Procedures
O3J	Beef carcass (steer/heifer/cow/bull)	CCP-1	[redacted]		

	[redacted]
CCP-2	
CCP-3	

	[redacted]
CCP-3B	

GENERAL HAZARD ANALYSIS, FLOW DIAGRAM AND HACCP

H1. Are all hazards reasonably likely to occur identified as appropriate? Yes

H2. Are all decisions made in the hazard analysis supported with documentation on file? Yes

H3. Why did you come to the conclusions in H1 and H2? Briefly explain how the answers in H1 and H2 were determined including the names of documents used.

At the step of receiving live cattle, the establishment addressed biological hazards of *E. coli* 0157:H7 and *Salmonella* as reasonably likely to occur. The establishment addressed the Sanitary Dressing Procedures to prevent contamination. The establishment addressed the final trim and antimicrobial carcass spray as a measure to be applied to prevent, eliminate, or reduce the hazard to an acceptable level. The establishment addressed chemical hazards of residues as reasonably likely to occur. The establishment indicated that the plant/FSIS records demonstrate residues have been a past problem. Pecos Valley Meat addressed their drug residue policy as a measure to prevent, eliminate, or reduce the hazard to an acceptable level.

At the step of stunning/bleeding, the establishment addressed biological hazards and was indicated as none at this step but does state that the hazard is likely to occur. The establishment addressed possible contamination from the hide. The establishment indicates that the hazard will be controlled at the final trim and antimicrobial spray as a measure to be applied to prevent, eliminate or reduce the hazard to an acceptable level. The establishment addressed BSE (Bovine Spongiform Encephalopathy) as a hazard reasonably likely to occur as

per USDA notice 4-04. The establishment addressed the BSE/SRM pre-requisite program as a measure to be applied to prevent, eliminate, or reduce the hazard to an acceptable level.

At the step of skin and drop head, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as reasonably likely to occur. The establishment addressed the potential pathogen contamination from gastrointestinal tract and potential fecal contamination from hide removal. The establishment addressed that employee will trim any visible ingesta or fecal contamination. The hazard will be controlled at head inspection table and antimicrobial spray as a measure to be applied to prevent, eliminate or reduce the hazard to an acceptable level.

At the steps of rod [redacted] and free and bag bung/tail switch cutoff, the establishment addressed hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed potential pathogen contamination from gastrointestinal tract and potential fecal contamination from bung cutout. The establishment addressed the hazards will be controlled at the final trim station and the antimicrobial carcass spray.

At the steps of remove udder and first leg, remove second leg, siding/marking pattern on hide, hide removal, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed potential fecal and/or milk contamination from hide removal. The establishment addressed that employee will trim any visible fecal and milk contamination. Also, will be controlled at final trim rail and antimicrobial carcass spray.

At the step of evisceration, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed possible contamination in intestines. The establishment addressed that the hazard will be controlled at final trim station and antimicrobial station. The establishment also addressed BSE as reasonably likely to occur and there could be possible contamination in the intestines. The establishment indicated that the hazard would be addressed in the SRM (specified risk materials) removal and disposition program.

At the split saw step, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed possible contamination from previous steps. The establishment indicated that the hazards will be controlled at final trim station. The establishment also addressed BSE as a hazard reasonably likely to occur by spinal cord contamination. The establishment addressed the hazard at the final trim station and indicated that the saw will be sanitized as needed to prevent cross contamination. The establishment also addressed the hazard with the SRM removal and disposition program.

At the final trim station, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed possible contamination from previous steps. Pecos Valley Meats addressed that this step is used to trim all visible contamination. Also, the establishment addressed BSE as a hazard reasonably likely to occur and there could possibly be contamination from the spinal cord. The establishment indicated that the hazard would be addressed in the SRM (specified risk materials) removal and disposition program.

At the step of QC Inspection, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed monitoring of zero tolerance for possible visible contamination. Pecos Valley Meats performs [redacted]. The establishment has identified this step as CCP-1.

At the step of antimicrobial spray carcass and variety meats, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed possible unseen pathogens. Pecos Valley Meats [redacted]. The establishment has identified this step as CCP-2.

At the step of chilling all products, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as reasonably likely to occur. The establishment addressed possible pathogen growth if product is not properly chilled. Pecos Valley Meats addressed [redacted]. The establishment has identified this step as CCP-3.

At the cold storage step, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* as hazards reasonably likely to occur. The establishment addressed pathogens reasonably likely to grow if room temperature climbs to over [redacted] Pecos Valley Meats addressed [redacted]. The establishment has identified this step as CCP-3B.

At the rinse head-wash tongue step, the establishment addressed biological hazards of *E. coli* O157:H7, *Salmonella* and BSE as hazards reasonably likely to occur. The establishment addressed possible ingesta contamination. Pecos Valley Meats addressed [redacted] The establishment has identified this step as CCP-1.

- At the steps of spray [redacted] and put product in cooler, the establishment does not include these steps in the hazard analysis, but the steps are included in the flow diagram. Even though the establishment has failed to address this step in the [redacted] is a CCP (CCP-2) and is being monitored. The establishment also has supporting documentation for the [redacted] This is a noncompliance with 9 CFR 417.2 (a) (1).

At the step of variety meats packaging, the establishment addressed biological hazards of *E. coli* O157:H7 and *Salmonella* outgrowth as hazards reasonably likely to occur. The establishment addressed possible pathogen outgrowth if product internal temperature is not maintained at or below [redacted] Pecos Valley Meats addressed maintaining product at or below [redacted] The establishment has identified this step as CCP-4B in the O3C Hazard Analysis.

- At the step of freeze variety meats, the establishment does not include this step in the hazard analysis, but this step is included in the flow diagram. Even though the establishment has failed to address this step in the Hazard Analysis, the establishment is monitoring and keeping records of the freezer temperatures. This is a noncompliance with 9 CFR 417.2 (a) (1).

H4. Does the plant use a prerequisite program(s)? Yes

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 03J and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.

Drug Residue Policy Program:

Pecos Valley Meats will cooperate fully with and support FSIS efforts to prevent violative chemical residues from entering the food supply. In the event FSIS inspection personnel, through agency testing, identify livestock, carcasses or products containing violative levels of chemical residues, Pecos Valley Meats will take

all necessary precautions to ensure these products do not enter commerce. The Drug Residue Policy is preventing a chemical hazard from occurring.

[redacted]

Drug Residue Policy:

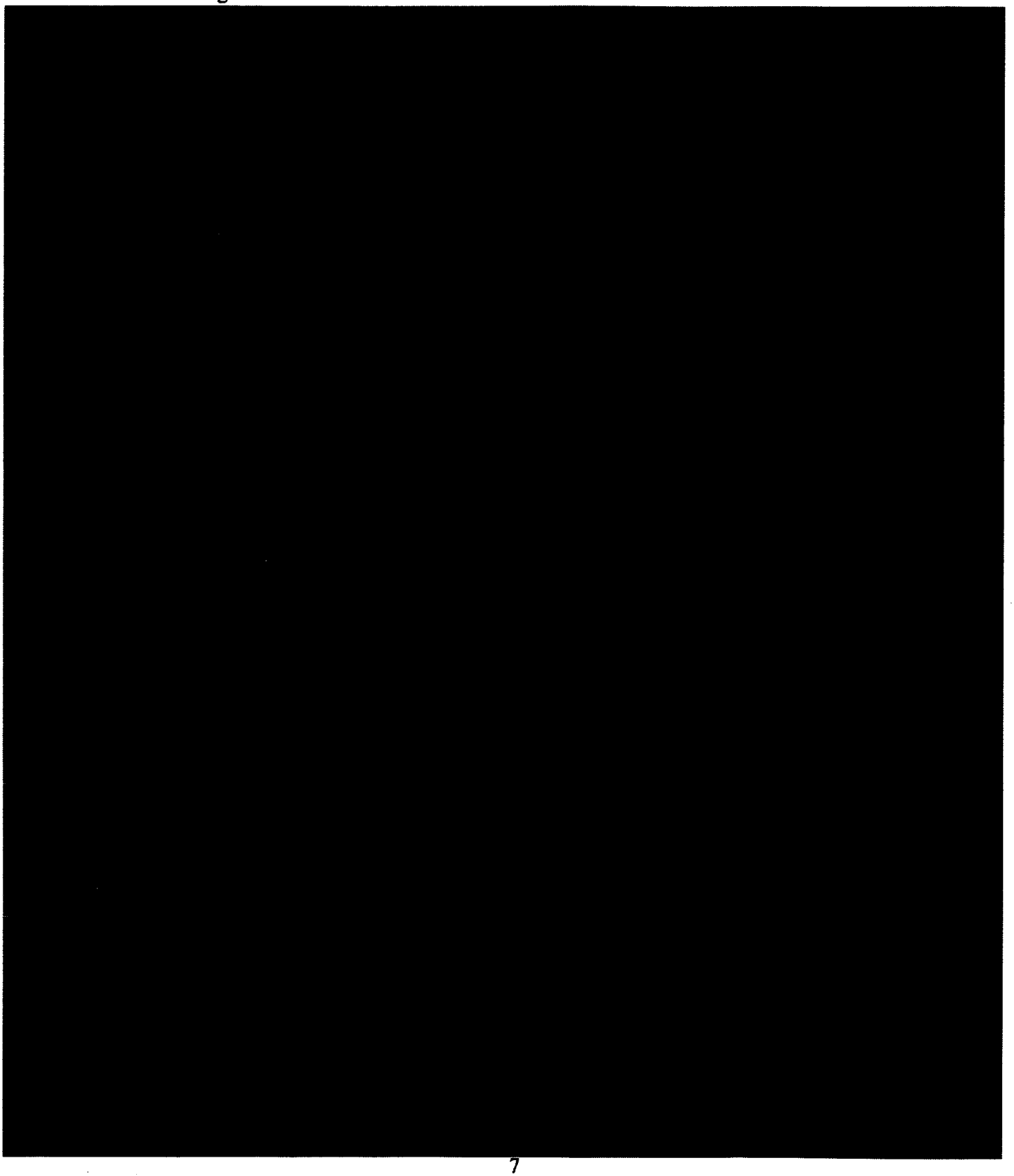
[redacted]

EIAOs [redacted] and [redacted] reviewed the establishment's Drug Residue records for the past 60 days (June 9, 2010 through August 9, 2010) and observed that the establishment was documenting Drug Residue Violation Letters to producers, which explained the importance of ensuring that all animals sent to slaughter, be free of drug residue.

Sanitary Dressing Procedures:

Pecos Valley Meats, Est. 07299, HACCP O3J Slaughter Meat

Pecos Valley Meats' sanitary dressing procedures are incorporated into the establishment's operational sanitation procedures for the slaughter floor. The Sanitary Dressing Procedures is preventing a biological hazard from occurring.



[redacted]

EIAOs [redacted] and [redacted] observed the employees on August 11, 2010, wash and sanitize hands as needed and sanitize their knives after each cut into the hide.

Procedures for Removal, Segregation and Disposition of Specific Risk Materials Identified in 9 CFR 310.22 Cattle 30 months Age or Older:

[redacted]

[redacted]

[redacted]

EIAOs [redacted] and [redacted] reviewed the establishment's Daily Operational Procedures Form KF 2 (Daily SRM Monitoring Log) from May 4, 2010 through August 5, 2010, and observed that the establishment was documenting the monitoring and disposition of SRMs along with the date, time, and QC initials. The record indicated that, '[redacted] as indicated on the Daily Operational Procedure Form PR 2. The form includes the date, time, and QC initials.

H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? No

H4c. Why did you come to this conclusion? Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may affect the production of safe product. N/A

H4d. If yes to H4, with the records reviewed, has the plant had a deviation from compliance with a prerequisite program? N/A

H4e. If yes to H4d, did it constitute a trend, and did the plant reassess? N/A

H4f. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes

H4g. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's Drug Residue records for the past 60 days (June 9, 2010 through August 9, 2010) and observed that the establishment was documenting Drug Residue Violation Letters to producers, which explained the importance of ensuring that all animals sent to slaughter, be free of drug residue.

EIAOs [redacted] and [redacted] observed the employees on August 11, 2010, wash and sanitize hands as needed and sanitize their knives after each cut into the hide.

EIAOs [redacted] and [redacted] reviewed the establishment's Daily Operational Procedures Form KF 2 (Daily SRM Monitoring Log) from May 4, 2010 through August 5, 2010, and observed that the establishment was documenting the monitoring and disposition of SRMs along with the date, time, and QC initials. The record indicated that, "[redacted] as indicated on the Daily Operational Procedure Form PR 2. The form includes the date, time, and QC initials.

H4h. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.

There are no additional findings regarding prerequisite programs.

H5. Are all steps in the process(s) included in the flow diagram? Yes

H6. Briefly discuss any regulatory noncompliance associated with a flow diagram.

EIAOs [redacted] and [redacted] reviewed the flow diagram for the Slaughter process and compared the flow diagram to actual product flow during Slaughter. EIAOs [redacted] and [redacted] found the flow diagram did match the actual Slaughter process within the facility.

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? Yes

H7a. Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion.

A review of the establishment's HACCP plan on August 12, 2010, revealed that all hazards that appear in the hazard analysis are adequately addressed by the establishment in the HACCP plan.

Answer the following series of questions to determine if the design of the HACCP plan meets all requirements of 9 CFR 417.

H8 Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits? Yes

H8a. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the CCPs in the HACCP plan and confirmed that the CCPs listed the monitoring procedures and frequencies.

CCP-1
Monitoring Procedures:

[redacted]

CCP-2
Monitoring Procedures:

[redacted]

CCP-3
Monitoring Procedures:

[redacted]

CCP-3B
Monitoring Procedures:

[redacted]

H8b. Are the monitoring procedures being performed as described in the HACCP plan? No

H8b1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 11 and 17, 2010, EIAOs [redacted] and [redacted] observed the QC perform CCP-1, [redacted] for two (2) carcasses and variety meats with a result of Zero (0) entered on the [redacted] Form. The QC documented the results on the "[redacted] Form CCP-1".

On August 13, 2010, EIAOs [redacted] and [redacted] observed the Plant Owner, Mr. Rick De Los Santos, perform the [redacted] for CCP-2. Mr. De Los Santos [redacted]

[redacted] and [redacted] observed the QC perform CCP-2, [redacted]

On August 19, 2010, EIAOs [redacted] and [redacted] observed the QC perform CCP-3, [redacted]. The QC used a [redacted]

On August 19, 2010, EIAOs [redacted] and [redacted] observed the QC perform CCP-3B, [redacted]

The following deficiencies were found while reviewing the establishment's records for May 4, 2010 through July 30, 2010:

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed on July 22, 2010, the QC did not indicate on the "[redacted] CCP-2" if the [redacted] was acceptable according to the HACCP plan for CCP-2. This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] CCP-2", the [redacted] This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On June 11 and 16, 2010, the QC did not document on the "[redacted] CCP-2", [redacted]. The records only indicated that the carcasses were acceptable or ok according to the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (3).

H8c. Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan? Yes

H8c1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1", "[redacted] CCP-2", and "[redacted] CCP-3 and CCP-3B" from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed that the establishment was performing the monitoring procedures at the frequencies specified in the HACCP plan.

H8d. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments? No

H8d1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the HACCP plan listed [redacted] for CCP-3 and CCP-3B. For CCP-3B, the establishment stated that "[redacted]."

- On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the HACCP plan for CCP-3B and observed that the establishment did not state a frequency for the thermometer calibration, but [redacted]. This is a noncompliance with 9 CFR 417.5 (a) (2).

H8e. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions? Yes

H8e1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the CCPs in the HACCP plan listed the direct observation of monitoring activities as the following:

CCP 1:

[redacted]

CCP 2:

[redacted]

CCP 3:

[redacted]

CCP 3B:
Verification of the room temperature will be performed once per week by coordinator or assigned QC.

H8f. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a) (3)? Yes

H8f1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the HACCP plan listed the procedures and frequencies for the review of records for CCP-1, CCP-2, CCP-3, and CCP-3B. The HACCP plan stated that "[redacted]".

H8g. Does the HACCP plan list product sampling as a verification activity? No

H8g1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] was advised by Mr. Rick De Los Santos, Plant Owner, this establishment does not list product sampling as a verification activity in the HACCP plan.

H8h. Are process-monitoring instrument calibration activities conducted as per the HACCP plan? Yes

H8h1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

[redacted]

H8i. Are direct observation verification activities conducted as per the HACCP plan? No

H8i1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's "[redacted] CCP-1", "[redacted] CCP-2", and "[redacted] CCP-3 and CCP-3B" records. The records were reviewed from May 4, 2010 through July 30, 2010 which revealed the following:

- On June 3 and 16, 2010 EIAOs [redacted] and [redacted] observed that the "[redacted] CCP-1" records lacked a variety meat direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

On August 11, 17, and 19, 2010, EIAOs [redacted] and [redacted] observed the QC perform direct observation on the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records.

H8j. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment? Yes

H8j1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records. The records revealed that the establishment was documenting the records review once per day as indicated in their HACCP plan.

On August 17, 2010, EIAOs [redacted] and [redacted] observed Mr. Rick De Los Santos, review the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records. Mr. De Los Santos reviewed the records in accordance with 9 CFR 417.5 (a)(3).

H8k. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP? Yes

H8k1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed that all the CCP records were designed and implemented in a manner to document the monitoring of the CCPs and critical limits. On August 13, 2010, EIAOs [redacted] and [redacted] reviewed 60 days (May 4, 2010 through July 30, 2010) of the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records and observed that the HACCP plan set out a recordkeeping system that documented the monitoring of the CCP.

H8l. Do the records contain actual values and observations obtained during monitoring? Yes

H8l1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed 60 days of records from May 4, 2010 through July 30, 2010, and observed that the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records contained actual values and observations as observed during monitoring.

H8m. Does the establishment have the supporting documentation for initial validation on file? No

H8m1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 18, 2010, Mr. Rick De Los Santos, Plant Owner informed EIAOs [redacted] and [redacted] that his establishment does not have the supporting documentation for initial validation on file. EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records of the Slaughter Meat HACCP plan from May 4, 2010, through July 30, 2010 and observed that the establishment continuously tested the adequacy of the procedures and limits set forth in their written HACCP plan including the review of records and are maintaining, at a minimum, the previous 60 days of validation records.

H8n. Does the establishment have the decision making documents associated with the selection of each CCP? Yes

H8n1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's decision making documents for the CCPs. The establishment provided EIAOs [redacted] and [redacted] with the following documents:

CCP-1: [redacted]

CCP-2: "[redacted]

CCP-3: [redacted]

CCP-3B: [redacted]

H8o. Do the documents explain why the establishment selected that location for the CCP? Yes

H8o1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

CCP-1: [redacted]

CCP-2: [redacted]

CCP-3: [redacted]. Bruce Tompkins, Ph D indicates that pathogens are more likely to grow during storage steps of the process.

CCP-3B: [redacted]

H8p. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards? Yes

H8p1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

A review of the establishment's Hazard Analysis and HACCP plan revealed that the establishment has established points in their process that will prevent, eliminate, or reduce to acceptable levels the identified hazards and are identified as CCP 1, CCP 2, CCP 3 and CCP 3B for the Slaughter HACCP plan. EIAOs [redacted] and [redacted] reviewed the establishment's supporting documents on August 16, 2010 and observed that the documents helped support their process.

H8q. Does the establishment have scientific, technical, or regulatory support for the critical limit? Yes

H8q1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

[redacted]

H8r. Does the support appear credible? Yes

H8r1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The documents offered by the establishment were published by widely known and reputable universities. The establishment also used a summary by FSIS (Food Safety and Inspection Service), as well as the widely used minimum growth temperatures document published by Dr. Bruce Tompkins, Ph D.

H8s. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? No

H8s1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

- The establishment did not have documents supporting the monitoring procedures and frequencies listed in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

H8t. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done? No

H8t1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

- The establishment did not have documents supporting the verification procedures and frequencies in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

H8u. If the establishment has supporting documents for these decisions, does the documentation support the decisions? N/A

H8u1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment did not have documents supporting the monitoring and verification procedures and frequencies listed in the HACCP plan.

H8v. Do the records document the monitoring of CCPs and their critical limits? Yes

H8v1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's records from May 4, 2010 through July 30, 2010, and confirmed the establishment was documenting the monitoring of CCP-1, CCP-2, CCP-3, and CCP-3B, and the critical limits. EIAOs [redacted] and [redacted] observed the monitoring of CCP-1, CCP-2, CCP-3, and CCP-3B on August 11, 17, and 19, 2010 and confirmed the establishment was properly monitoring and documenting the CCP values on the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3/CCP-3B" records.

H8w. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan? No

H8w1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records from the dates of May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] confirmed that for CCP-1, CCP-2, CCP-3, and CCP-3B, the establishment is [redacted] for CCP-1, CCP-2, CCP-3, and CCP-3B as indicated in the HACCP plan. The exceptions are as follows:

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed on July 22, 2010, the QC did not indicate on the "[redacted] if the [redacted] was acceptable according to the HACCP plan for CCP-2. This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] for CCP-2 the tag I.D. for [redacted]). This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On June 11 and 16, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]. The records only indicated that the carcasses were acceptable or ok according to the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (3).

EIAOs [redacted] and [redacted] observed the monitoring of CCP-1, CCP-2, CCP-3, and CCP-3B on August 11, 17, and 19, 2010 and confirmed the establishment was properly monitoring and documenting the CCP values as indicated in the HACCP plan for CCP- 1, CCP-2, CCP-3 and CCP-3B.

H8x. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, or a means by which the records can be associated with a specific production, and the date the record was made? No

H8x1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records from the dates of May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] confirmed that for CCP-1, CCP-2, CCP-3, and CCP-3B, the [redacted] for CCP-1, CCP-2, CCP-3, and CCP-3B as indicated in the HACCP plan. The exceptions are as follows:

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] for CCP-2 the tag I.D. for [redacted]. This is a noncompliance with 9 CFR 417.5 (a) (3).

H8y. Are the verification procedures and results of those procedures documented? No

H8y1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 17, 2010, EIAOs [redacted] and [redacted] observed the performance of direct observation of monitoring activities, and the records review verification procedures. EIAOs [redacted] confirmed the establishment was documenting the direct observation of monitoring, and the records review on the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records and the "[redacted]". EIAOs [redacted] and [redacted] reviewed all the CCP records from the dates of May 4, 2010, through July 30, 2010, and confirmed the establishment was documenting the performance of the direct observation of monitoring and records review verification, and documenting the results of the verification except for the following:

- On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed that the "[redacted] CCP-1" records on June 3 and 16, 2010, that the [redacted] during those weeks as indicated in the HACCP plan. This is a noncompliance with 9 CFR 417.4 (a) (2) (ii).

H8z. Is the time recorded when the verification activity was performed? Yes

H8z1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records from the dates of May 4, 2010, through July 30, 2010, as well as observations of the verification procedures on August 17-19, 2010, confirmed the establishment was documenting a time that each direct observation, records review verification task was being performed.

H8aa. Does the record contain the date the record was made? Yes

H8aa1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1", "[redacted] CCP-2", and the "[redacted] CCP-3 and CCP-3B" records from the dates of May 4, 2010, through July 30, 2010, as well as observations of the verification procedures on August 16 and 17, 2010 confirmed the establishment was documenting the date that each record was made.

H8bb. Are the process-monitoring calibration procedures and results being recorded? Yes

H8bb1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

[redacted]

H8cc. Was each entry on the record made at the time the event occurred? Yes

H8cc1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the calibration of thermometers on August 17, 2010, and confirmed the establishment was documenting the calibration of the monitoring device immediately after the calibration procedures were completed.

H8dd. Does each entry include the time? Yes

H8dd1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

A review of the calibration records from the dates of June 10, 2010, through August 6, 2010, confirmed the establishment was documenting a time for each calibration procedure.

H8ee. Was each entry on the record signed or initialed by the establishment employee making the entry? Yes

H8ee1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the calibration of thermometers on August 17, 2010, and confirmed the designated employee documented the calibration on the thermometer calibration log, and initialed the form with his initials.

H8ee. Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products? Yes

H8ee1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment maintains records for the required amount of time (1 year). Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment keeps records since 2001. On August 17, 2010, EIAOs [redacted] and [redacted] verified the Slaughter records from April 9, 2009 through April 10, 2010 were onsite.

H8ff. Are the records kept on-site for 6 months? Yes

H8ff1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment maintains records for the required amount of time (1 year). Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment keeps records since 2001. On August 17, 2010, EIAOs [redacted] and [redacted] verified the Slaughter records from April 9, 2009 through April 10, 2010 were onsite.

H8gg. If the records are stored off-site after 6 months, can they be retrieved in 24 hours? Yes

H8gg1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that he has kept the Slaughter records on the property since 2001.

H8hh. Has the establishment reviewed the records associated with the production of the product, prior to shipment? Yes

H8hh1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the "Pre-shipment Review Log" records from May 7, 2010 through August 13, 2010, and observed that the establishment reviewed the records prior to shipment. On August 17, 2010, EIAOs [redacted] and [redacted] observed the QC conduct the pre-shipment review of records prior to the shipment of [redacted]

[redacted]

H8ii Does the establishment list corrective actions in its HACCP plan that meet the requirements under 417.3? Yes

H8ii1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's HACCP plan and observed that the establishment listed corrective actions that meet the requirements under 417.3.

H8jj. Is a responsible party identified? Yes

H8jj1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and observed that the establishment identifies the HACCP Coordinator as the responsible person for corrective actions.

H8kk. If corrective actions have been taken by the plant, were those corrective actions effective? No

[redacted]

H8ll. How many times within the last 60 days did the establishment have deviations from CCPs?

__ 0 times

_X_ 1-2 times
__ 3-5 times
__ >5 times

H8mm. Has a reassessment been conducted to meet the annual reassessment requirement? Yes

H8mm1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP reassessment log and confirmed the last reassessment of the HACCP O3J Slaughter plan was performed on January 16, 2010, by Rick De Los Santos, Plant Owner to meet the annual reassessment requirements.

H8nn. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis? Yes

H8nn1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

A review of the Slaughter HACCP plan and HACCP reassessment showed the establishment reviews all changes in the process and considered the developments that could affect the products produced. The establishment increased the [redacted] for CCP-2.

H8oo. Has change occurred that could affect the hazard analysis or HACCP plan? Yes

H8oo1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment increased the [redacted] for CCP-2.

H8pp. Did the establishment reassess? Yes

H8pp1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP reassessment log and confirmed the last reassessment of the HACCP O3J Slaughter plan was performed on January 16, 2010, by Rick De Los Santos, Plant Owner to meet the annual reassessment requirements.

H8qq. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately? N/A

H8qq1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

N/A

H9. Does the execution of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? No

H9a. Describe the analysis conclusions that led to your answer in H9. Describe all non-compliance finding. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

[redacted]

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed on July 22, 2010, the QC did not indicate on the "[redacted] if the [redacted] spray was acceptable according to the HACCP plan for CCP-2. This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]. This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On June 11 and 16, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]. The records only indicated that the carcasses were acceptable or ok according to the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (3).

- On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the HACCP plan for CCP-3B and observed that the establishment did not state a frequency for the thermometer calibration, but stated the frequency of thermometer calibration under the monitoring procedures. This is a noncompliance with 9 CFR 417.5 (a) (2).

- On June 3 and 16, 2010 EIAOs [redacted] and [redacted] observed that the "[redacted] CCP-1" records lacked a variety meat direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

- The establishment did not have documents supporting the monitoring procedures and frequencies listed in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

- The establishment did not have documents supporting the verification procedures and frequencies in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]. This is a noncompliance with 9 CFR 417.5 (a) (3).

[redacted]

- The Pre-shipment Review was being performed and documented in confirming that all CCPs were met for the production lots produced under the Slaughter HACCP plan. The reviewer however, failed to note the critical limit deviation documented on the "[redacted] CCP-3 and CCP-3B" record dated on July 17, 2010, for the [redacted]. Moreover, the reviewer failed to take any corrective actions. This is a noncompliance with 9 CFR 417.5 (c).

G2. What PR HACCP *Salmonella* category is the establishment currently in?

__Category 1
__Category 2
_X_Category 3
__Not applicable (specify in G2a.)

G2a. If answer Category 2 or 3, what, if anything, has the plant done or proposed to do in order to move to Category 1? Yes, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that he has added more refrigeration to his establishment as well as backup refrigeration in case it goes out. Mr. De Los Santos also informed EIAOs [redacted] and [redacted] that the [redacted], to help decrease the outgrowth of *Salmonella*.

G3. Does the establishment conduct its own testing for *Salmonella* spp.? No

G3a. Does the plant have documented sample collection and testing procedures for *Salmonella* spp.? No

G3b. Why did you come to these conclusions? Describe the observations and/or documents used to reach your decision. Briefly describe any sampling and testing procedure for *Salmonella* spp. used by the establishment. **Analysis:** Include any weaknesses in the method taking into account sample size, frequency, aseptic technique, method fit for intended use, validation, sensitivity of detection, reliability, and if the procedures are being implemented as written.

The establishment does not test for Salmonella spp., but they test for Generic *E. coli* on carcasses and *E. coli* O157:H7 on their boneless beef trim in the Raw, Not Ground process (O3C).

G4. Does the establishment test product, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, *Enterobacteriaceae*)? If yes, check all that apply

[redacted]No
Carcass before intervention
Carcass after intervention
Slaughter Equipment

Slaughter area
Others, please specify

G4a. Analysis: does the establishment use testing data for decision making and how does the establishment use the data? Yes

G4b. Why did you come to this conclusion? Describe the observations and/or documents used to reach your decision. If no, does this bring into question the decisions made in the hazard analysis?

The establishment uses the test results of the Generic *E. coli* to determine the effectiveness of their [redacted]).

G5. Does the establishment have written generic *E. coli* procedures? Yes

G5a. Which of the following sampling methods does the establishment use? Check all that apply.

[redacted]Cattle, Excision, m/M
Cattle, Sponging, Statistical process control
Swine, Excision, m/M
Swine, Sponging, Statistical process control
Hide-On Cattle, Excision, m/M
Other Hide-on Carcasses, Sponging, Statistical process control
Sheep & Goats, Sponging, Statistical Process Control
Other, Please specify non-compliance

G6. What sampling frequency is the plant using?

[redacted]Regulatory frequency
Alternative sampling frequency

G6a. Does the establishment have adequate justification for an alternative sampling frequency per the regulation? N/A

G6b. Why did you come to these conclusions? Describe the observations and/or documents used to reach your decision.

The establishment uses the regulatory frequency for the sampling of Generic *E. coli*.

G7. Does the establishment have support for the sampling procedure and testing method? Yes

G8. Describe the generic *E. coli* sample collection and testing procedures. **Analysis:** Include any weaknesses in the method taking into account sample size, frequency, aseptic technique, method fit for intended use, validation, sensitivity of detection, and reliability.

[redacted]

[redacted]

EIAOs [redacted] and [redacted] reviewed the establishment's Generic *E. coli* testing results and observed that the establishment took Generic *E. coli* samples on July 28, 2010 and August 5, 2010. The results were < 0.08 cfu/sq cm for Generic *E. coli* and were documented on a certificate of analysis from [redacted] and [redacted] and on a control chart.

G9. Is the establishment implementing generic *E. coli* procedures as written? Yes

G9b. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. Is there non-compliance with 9 CFR 310.25?

On August 12, 2010, EIAOs [redacted] and [redacted] reviewed the establishment's Generic *E. coli* Testing Procedures and observed that the establishment will collect the sample by randomly picking a carcass by using numbered carcasses from previous day's slaughter. [redacted] *E. coli* binder.

EIAOs [redacted] and [redacted] reviewed the establishment's Generic *E. coli* testing results and observed that the establishment took Generic *E. coli* samples on July 28, 2010 and August 5, 2010. The results were < 0.08 cfu/sq cm for Generic *E. coli* and were documented on a certificate of analysis from [redacted] and [redacted] and on a control chart.

G10. Over the past 60 days, has the establishment routinely met their limits as determined by either m/M or statistical process control? No

G10a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the Generic *E. coli* records and observed that the establishment only had two testing dates (July 27, 2010 and August 5, 2010) and results within the past 60 days. Upon an interview on August 9, 2010, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment was suspended by the Denver District Office for failure to conduct Generic *E. coli* testing starting the month of June.

G10b. If No, are there any correlations with fecal failure NRs, deviations from the zero tolerance critical limit, sanitary dressing failures, rapid turnover of employees, or positive FSIS sampling results for the same time period? Yes

G10c. Briefly describe any correlations, corrective actions taken by the establishment, and possible regulatory non-compliance.

EIAOs [redacted] and [redacted] reviewed the Generic *E. coli* records and observed that the establishment only had two testing dates (July 27, 2010 and August 5, 2010) and results within the past 60 days. Upon an interview on August 9, 2010, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment was suspended by the Denver District Office for failure to conduct Generic *E. coli* testing starting the month of June.

G11. Does the plant actively use generic *E. coli* test results for decision making purposes? Yes

G11a. Why did you come to this conclusion in G11? Describe the observations and/or documents used to reach the decision. How does the decision making, or lack of, affect process control? Briefly describe any non-compliances found while reviewing the establishment's generic *E. coli* testing program.

The establishment uses the test results of the Generic *E. coli* to determine the effectiveness of their antimicrobial spray ([redacted] of 3%). EIAOs [redacted] and [redacted] reviewed the Generic *E. coli* records on July 27, 2010, and August 5, 2010, and observed that the results were < 0.08 cfu/sq. cm.

G12. Does the establishment accept returned product? No

G12a. Describe how the establishment utilizes returned product.

The establishment does not accept returned product.

G13. Does the establishment rework product? No

G13a. Describe how the plant controls the use of rework product.

The establishment does not rework product.

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes

B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.

[redacted]HACCP
_SSOP
Pre-requisite

B3. Does the establishment apply any of the following decontamination procedures prior to hide removal?

[redacted]No
_Pre-slaughter animal wash
_Pre-slaughter head wash
Post-slaughter dehairing
Pre-dehiding carcass wash
Others, please specify (free text box)

B4. Does the establishment have documentation of employee training in any of the following areas? If yes, check all that apply.

[redacted]No
_Proper hide removal
_Proper evisceration procedures
_Adequate sanitation of knives and sharpening steels
_Importance of minimizing cross contamination

SANITARY DRESSING (all species)

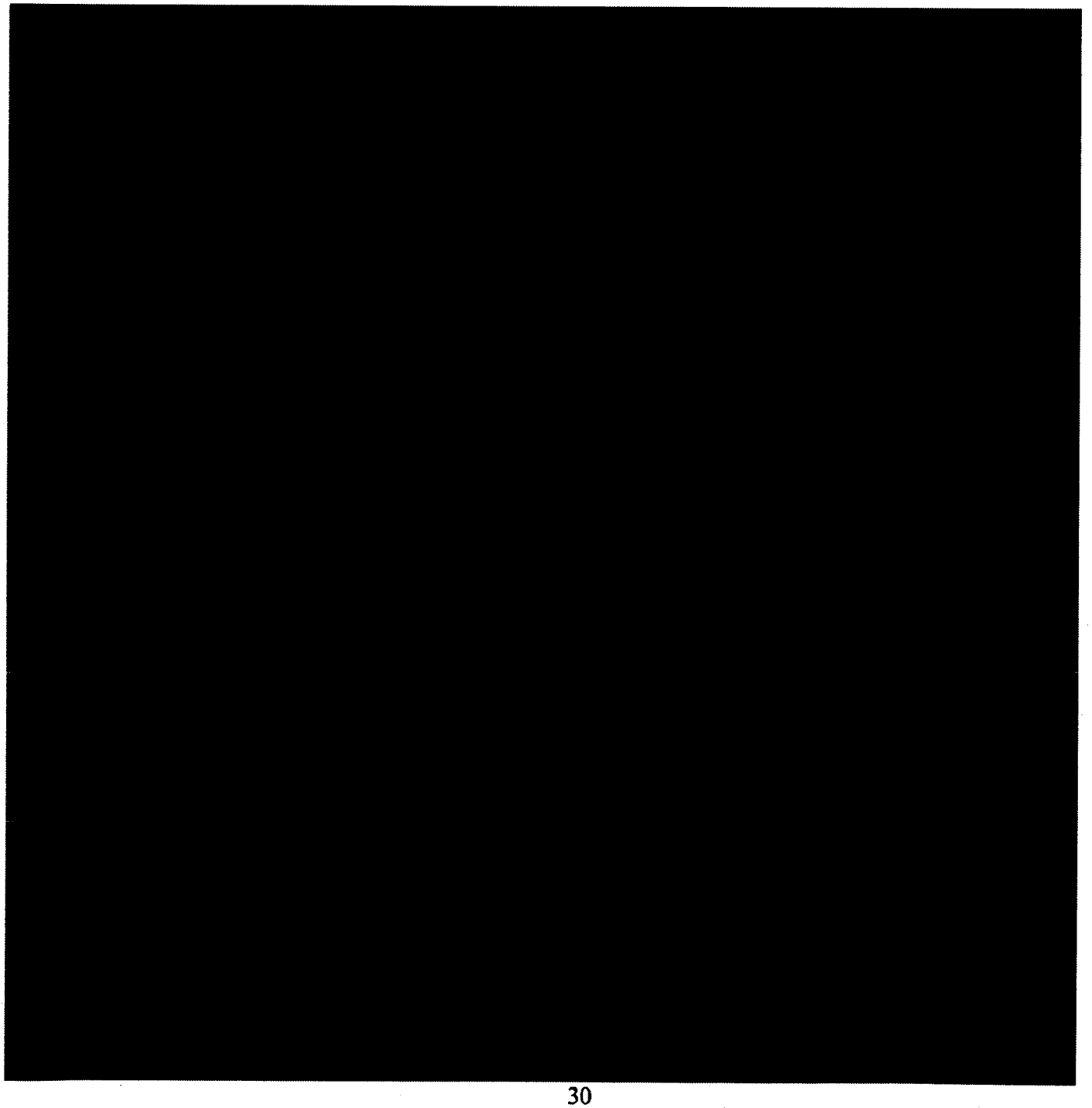
SD1. Are there written job descriptions for each job position in the sanitary dressing procedure process (from stunning to final wash)? Yes

SD1a. If yes, are the job descriptions used as a means to train employees and monitor their performance to assure sanitary dressing procedures are being followed? Yes

SD1b. If yes, are the job descriptions being implemented as written? Yes

SD1c. Why did you come to the conclusions in SD1, SD1a and SD1b? Describe the observations and/or documents used to reach the decisions.

EIAOs [redacted] and [redacted] reviewed the Sanitary Dressing Procedures on August 12, 2010. The Sanitary Dressing Procedures consisted of the following:



[redacted]

EIAOs [redacted] and [redacted] observed the employees on August 11 and 17, 2010, wash and sanitize hands as needed and sanitize their knives after each cut into the hide.

SD2. If there are no written job position procedures, how are the employees trained and monitored to assure sanitary dressing procedures are being followed? N/A

SD3. Does the establishment dehide carcasses? Yes

SD3a. What kind of sanitary dressing procedures does the establishment employ in the de-hiding area? (i.e. two knife rotation, pattern trimming, sanitizing of gloves, equipment & aprons)? Are the employees following them?

The establishment performs the following sanitary dressing procedures for de-hiding carcasses:

[redacted]

[redacted]

EIAOs [redacted] and [redacted] observed the employees on August 11 and 17, 2010, wash and sanitize hands as needed and sanitize their knives after each cut into the hide.

SD3b. Do the carcasses travel down the rail in such a way that hide-on carcasses pass by partially de-hided carcasses in close enough proximity to touch or have the potential for causing cross contamination? (i.e. bumping or swinging carcasses)? No

SD3c. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the employees on August 11 and 17, 2010, manually push the carcasses on a single rail system and observed no overlap of carcasses.

SD5. Are their procedures in place to limit traffic from high contamination areas to low contamination areas? Yes

SD5a. If no, are there procedures in place to ensure that adequate measures are taken to prevent cross-contamination from high contamination areas to low contamination areas? N/A

SD5b. Why did you come to the conclusion in SD5 and SD5a? Describe the observations and/or documents used to reach the decisions.

EIAOs [redacted] and [redacted] observed employees on August 11 and 17, 2010, move from a high contamination area to a low contamination area once the carcass had been completely dehided. The employees washed down and the QC employee changed his frock in order to start the evisceration step.

INTERVENTIONS and VALIDATION (all species)

IV1. Does the establishment apply any food safety hazard interventions on carcasses? check all that apply

[redacted]
No Intervention
Chlorine
Hot Water Rinse
Organic Acid
Lactoferrin
Steam vacuum
Steam pasteurization
Peroxyacid (Inspexx)
Acidified sodium chlorite
Acidified calcium sulfate
Irradiation
Verify® fecal contamination equipment
Carcass Chilling
Metal detection
Others, please specify:

Pecos Valley Meats, Est. 07299, HACCP O3J Slaughter Meat

Note: The next 11 questions should be answered for each answer chosen in the above question other than "No Intervention"

IV1a. Is the intervention included in any of the following? Check all that apply.

[redacted]
HACCP Plan
Sanitation SOP
Prerequisite Program
GMP
Other, please specify

IV1b. Is the intervention validated and documented? Yes

IV1c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? Yes

IV1d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? Yes

IV1e. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? Yes

IV1f. If the critical variables, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? No

IV1g. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, procedure or equipment are different? No

IV1h. Did the establishment initially test for the adequacy of the intervention to reduce pathogenic organisms and fecal contamination? Yes

IV1i. Does the establishment have a rational basis or data to show that the reduction of pathogenic microorganisms and/or fecal contamination by the intervention is sufficient to control the level of contamination that may occur on carcasses? Yes

IV2. Why did you come to the conclusions in IV1b-i ? Describe the observations and/or documents used to reach the decisions. Further describe interventions the establishment has in place addressing pathogenic organisms, milk, ingesta and fecal contamination that were addressed in the questions in this section.

[redacted]

[redacted]

SAMPLING AND TESTING (Beef Only)

ST1. Does the establishment sample carcasses for *E. coli* O157:H7? No

ST1a. Does the establishment have support documented and filed for the sample collection procedure? N/A

ST1b. Briefly describe the sample collection procedure and support associated with the carcass sampling procedure. **Analysis:** Are they being followed as written? Are there weaknesses with the procedure (frequency, test portion, fit for intended use, aseptic technique etc.) that may bring into question decisions made in the hazard analysis?

N/A

ST1c. What microbiological method does the establishment use to test carcasses for *E. coli* O157:H7? N/A

ST1d. Does the establishment have support documented and filed for the testing procedure? N/A

ST1e. Why did you come to the conclusions in ST1a-d? Describe the observations and/or documents used to reach the decision. Briefly describe the microbiological method and support associated with the carcass testing procedure. Analysis: Are they being followed as written? Are there weaknesses with the method (test portion, fit for intended use, validation, sensitivity of detection, and reliability etc.) that may bring into question decisions made in the hazard analysis? N/A

ST1f. Based on the supporting documentation, is the sampling and testing procedure adequate to detect low levels of *E. coli* O157:H7 on carcasses? N/A

ST1g. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. N/A

ST1h. Does the establishment hold the sampled lot of product pending test results? N/A

ST1i. Regarding the establishment's sampling program: the establishment has had __0__ number of positive sample results from __0__ samples in the last 6 months.

ST2. Has the establishment been identified in the STEPS database as a supplier of *E. coli* O157:H7 positive product in the last 12 months? No

ST3. Does the plant have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? N/A

ST3a. Describe the corrective action procedures. N/A

SPECIFIED RISK MATERIALS (SRM) 9 CFR 310.22 (Beef Only)

SRM1. Does the establishment have a written plan for the removal of identified SRM materials? Yes

SRM2. Does the establishment receive cattle 30 months of age and older? Yes

SRM2a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

Mr. Rick De Los Santos, Plant Owner informed EIAOs [redacted] and [redacted] that his establishment only receives cattle 30 months of age and older. EIAOs [redacted] and [redacted] reviewed the establishment's "Procedures For Removal, Segregation and Disposition of Specific Risk Materials Identified in 9 CFR 310.22" and observed that the procedures stated, "[redacted]. All SRMs will be removed, segregated, and disposed".

SRM3. Where is the SRM control system located? Check all that apply

[redacted]
HACCP Plan
nitation SOP
Prerequisite Program
MP
her, please specify

Ante-mortem:

SRM4. Does the establishment handle all cattle as if they were 30 months of age and older? Yes

SRM5. Has the establishment developed procedures to identify through appropriate documentation or dentition examination whether cattle to be slaughtered are 30 months of age and older? Yes

SRM5a. Are the records acceptable for determining age? Yes

SRM5b. Why did you come to the conclusions in SRM5 and SRM5a? Describe the observations and/or documents used to reach your decisions.

EIAOs [redacted] and [redacted] observed that the establishment had Appendix 1: [redacted]

SRM6. Does the establishment segregate cattle determined to be 30 months of age and older from younger cattle? N/A

SRM7. What controls has the establishment developed and implemented to identify *non-ambulatory* cattle and handle them appropriately?

On August 18, 2010, EIAOs [redacted] and [redacted] interviewed Plant Owner, Mr. Rick De Los Santos, which revealed that the establishment will shock the cattle a maximum of two (2) times with the hot shock and if the cattle does not ambulate the establishment will condemn the cattle and denature the carcass. If the cattle has gone through ante-mortem and becomes non-ambulatory in the pen, the establishment will notify the FSIS Veterinarian of the non-ambulatory cattle.

SRM8. Is the establishment complying with the prohibition on injecting compressed air into the cranium of cattle during stunning (9 CFR 310.13 and 313.15)? Yes

SRM8a. Describe the ante-mortem SRM control program. Describe any non-compliance.

Mr. Rick De Los Santos, Plant Owner informed EIAOs [redacted] and [redacted] that his establishment only receives cattle 30 months of age and older. EIAOs [redacted] and [redacted] reviewed the establishment's "Procedures For Removal, Segregation and Disposition of Specific Risk Materials Identified in 9 CFR 310.22" and observed that the procedures stated, "[redacted]. All SRMs will be removed, segregated, and disposed".

Post Mortem:

SRM9. How are the carcasses of cattle 30 months of age or older identified?

The establishment identifies cattle 30 months of age or older by dentition. EIAOs [redacted] and [redacted] observed that the establishment had Appendix 1: [redacted]

SRM10. Can cattle carcasses 30 months of age or older be identified in coolers, at shipping, and at boning? Yes

SRM11. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

[redacted]

SRM Removal (All cattle)

SRM 12. Does the establishment have a written plan in place for the removal, segregation and disposal of tonsillar material, including head dressing procedures that include removal of the tongue and its associated lymph nodes, and visible tonsils? Yes

SRM12a. Is the procedure being implemented as it is written? Yes

SRM12b. Why did you come to the conclusions in SRM12 and SRM12a? Describe the observations and/or documents used to reach the decisions.

Tongues will be removed and a transverse cut will be made along the back of the tongue after the last vallate papillae to effectively remove lingual tonsils, this procedure will be done at head inspection station. EIAOs [redacted] and [redacted] observed employees on August 11 and 17, 2010, remove the tongue from the head properly.

SRM13. Does the establishment remove the entire small intestines to ensure effective removal of the distal ileum? Yes

SRM13a. Does the establishment remove the distal ileum and use the remainder of the small intestines for human food? No

SRM13b. If the establishment removes the distal ileum and uses the rest of the small intestine for human food, is the distal ileum removed in accordance with 9 CFR 310.22 (a) (3)? N/A

SRM13c. Why did you come to the conclusions in SRM13, SRM13a, and SRM13b? Describe the observations and/or documents used to reach the decisions.

The establishment removes the entire small intestines and does not use the small intestines for human food. The small intestines are disposed of and condemned.

SRM14. Are tongues trimmed correctly and saved? Yes

SRM14a. What type of procedure is used to trim tongues? Check all that apply.
[redacted] Hand / Knife trimming
[redacted] Mechanical trimming
[redacted] Other, please describe

SRM14b. Why did you come to the conclusions in SRM14 and SRM14a? Describe the observations and/or documents used to reach the decision. Describe the procedure used in tongue trimming.

EIAOs [redacted] and [redacted] observed employees correctly trimming and saving tongues. [redacted]

SRM15. Is the establishment disposing of all cattle carcasses, carcass parts, and other products contaminated with SRMs in accordance with 9 CFR 314.1 and 314.3? Yes

SRM15a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment denatures and disposes all SRMs in accordance with 9 CFR 314.3. On August 13, 2010, EIAOs [redacted] and [redacted] observed that, on ante-mortem, the establishment denatured and disposed of a cow according to their Humane Handling and 9 CFR 314.3. Also, on August 11, 2010, EIAOs [redacted] and [redacted] observed the denaturing of two heads during post mortem inspection.

SRM Removal and Segregation from cattle less than 30 months of age:

SRM16. Does the establishment harvest market heads? No

SRM16a. If yes, does the establishment have control measures in place to ensure that all visible tensile material is removed prior to shipping the market heads? N/A

SRM16b. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment does not harvest market heads.

SRM Removal and Segregation from cattle 30 months of age and older:

SRM17. Does the establishment have a written procedure in place that addresses the removal of the vertebral column? Yes

SRM17a. Is the procedure implemented as it is written? Yes

SRM17b. Why did you come to the conclusion in SRM 12 and SRM 12a? Describe the observations and/or documents used to reach the decision. Describe the procedure used in removal of the vertebral column.

[redacted]

On August 11 and 17, 2010, EIAOs [redacted] and [redacted] observed employees properly remove the vertebral column as stated in their SRM Program.

SRM18. Is the establishment disposing of all cattle carcasses, carcass parts, and other products contaminated with SRMs, including those associated with the head (skull, brain, eyes, trigeminal ganglia), spinal cord, vertebral column and intestines in accordance with 9 CFR 314.1 and 314.3? Yes

SRM18a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment denatures and disposes all SRMs in accordance with 9 CFR 314.3. On August 13, 2010, EIAOs [redacted] and [redacted] observed that, on ante-mortem, the establishment denatured and disposed of a cow according to their Humane Handling and 9 CFR 314.3. Also, on August 11, 2010, EIAOs [redacted] and [redacted] observed the denaturing of two heads during post mortem inspection.

Cross Contamination:

SRM19. Is the establishment segregating product by whether the cattle was 30 months of age and older at the time of slaughter in accordance with 9 CFR 310.22? No

SRM19a. If yes, segregation occurs, is dedicated equipment used to cut through SRMs? N/A

SRM19b. If dedicated equipment is not used, does the establishment clean and sanitize equipment, including the splitting saw prior to use on cattle younger than 30 months? N/A

SRM19c. Why did you come to the conclusions in SRM19, SRM19a, and SRM19b? Describe the observations and/or documents used to reach the decision. What controls has the establishment implemented to ensure that SRMs do not contaminate edible product?

[redacted]

SRM Program

[redacted]

SRM20. Is the establishment properly reconditioning the cattle carcasses or head by knife trimming when on-line inspection personnel observe visible and identifiable SRMs on edible portions of the product? Yes

SRM20a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment's SRM program states the following: [redacted]

Control Plan:

SRM21. Does the establishment have written procedures for when either the establishment or FSIS determines:

(1) that the establishment's procedures for the removal, segregation, and disposition of SRMs have failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and properly disposed of

Or

(2) the implementation or maintenance of such procedures, has failed to ensure that such materials are adequately and effectively removed from the carcass of cattle, segregated from edible materials, and properly disposed of? Yes

SRM21a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment's SRM program states the following: [redacted]

SRM22. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the SRMs, and any corrective actions taken? Yes

SRM22a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-1" records from May 4, 2010 through July 30, 2010, and observed that the establishment was maintaining daily records to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of the SRMs.

SRM23. Is the establishment retaining records for at least one year and making the records accessible to FSIS? Are these records maintained at the establishment for at least 48 hours following completion, and made available to FSIS within 24 hours of request? Yes

SRM23a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

On August 17, 2010, EIAOs [redacted] and [redacted] verified the Slaughter records from April 9, 2009 through April 10, 2010 were onsite. These records are maintained at the establishment for at least 48 hours following completion, and made available to FSIS within 24 hours.

Shipping:

SRM24. When shipping cattle carcasses or parts that contain SRM vertebral columns, does the establishment maintain control of the carcasses or parts while they are in transit [e.g., through company seals or ensures that the carcasses or parts move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1)] as provided in FSIS Notice 68-05? Yes

SRM24a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

[redacted]

SRM25. Are cattle carcasses or parts containing SRMs identified by a method that will transfer with the carcass during shipping? Yes

SRM25a. Why did you come to the conclusion in SRM25? Describe the observations and/or documents used to reach the decision. Describe the shipping method.

[redacted]

SRM26. Describe any further SRM controls employed by the establishment and any non-compliance.

[redacted]

[redacted]

ANIMAL DRUG AND BIOLOGICAL RESIDUES (all species)

AR1. Does the establishment have a residue control program? Yes

AR1a. Why did you come to the conclusion in AR1? Describe the observations and/or documents used to reach the decision. If yes, describe the program.

On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the establishment's Drug Residue Policy. The policy is as follows:

[redacted]

[redacted]

[redacted]

Drug Residue Policy:

[redacted]

AR2. Has the establishment identified animal drug or biological residues as a hazard reasonably likely to occur? Yes

AR2a. If no, has the establishment performed a reassessment in accordance with 9 CFR 417.4, and 69 FR 76884, HACCP Reassessment for Slaughterers of Young Calves 12/23/04, located at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-017N.htm? N/A

AR2b. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the Hazard Analysis on August 12, 2010, and observed that the establishment identified a chemical hazard of residues as a hazard reasonably likely to occur.

AR2c. Describe the control(s) in place and documentation available to support the premise that animal drugs or biological residues are not a hazard reasonably likely to occur. N/A

AR2d. Describe how is the hazard is controlled in their HACCP System (HACCP plan, Sanitation SOP, or prerequisite program).

[redacted]

AR3. Are animal health records available that provide documentation on what animal drugs were administered, when and for what purpose? No

AR4. What type of animal identification system is the establishment using? Check all that apply

[redacted]he system is followed through slaughter and inspection in accordance with 9CFR 310.2.
[redacted]he system is designed in a way that would provide for trace-back to the producer.

AR4a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. Describe the animal identification system used.

On August 19, 2010, EIAOs [redacted] and [redacted] interviewed the Plant Owner, Mr. Rick De Los Santos which revealed that the establishment has a system which allows it to trace the animal back to the producer. The establishment has the seller to sign a livestock purchase form which identifies the livestock by kind, color, back/ear tag and brand. The purchase form has the seller's name, address and telephone number as well as the following statement: I am the owner of these livestock which I hereby bargain, grant, sell and convey unto the purchaser and warrant and defend the title thereto, and said livestock are free and clear of all liens and are free and clear of all drug residue to the best of our knowledge.

AR5. Has the establishment, in the past 12 months, received a "Notification" from USDA for violative levels of animal drug residues? Yes

AR5a. If yes, what steps has the establishment taken to prevent this from reoccurring?

The establishment followed their Drug Residue Policy and sent out letters to the producers that were indicated as in violation of drug residue policy.

AR5b. If yes, is there a system in place to notify the supplier in writing of the animal(s) that had violative residue findings? Yes

AR5c. If yes, does the written notice to the supplier include discussions on the seriousness of selling and purchasing animals that contain both high and violative levels of animal drugs? Yes

AR5d. If yes, has the establishment supplied FSIS the name and address of the supplier? Yes

AR6. Is the establishment aware of the "Repeat Violators Alert List" (RVAL) posted on the USDA website at: http://www.fsis.usda.gov/Science/Chemistry/index.asp? Yes

AR7. Is the establishment involved with any voluntary residue avoidance program offered by a professional or state-certified organization? No

AR8. Does the establishment slaughter non-ruminating veal calves? No

AR9. Is there documentation that verifies the age of the veal calf at time of slaughter? N/A

AR10. Analysis: Describe the establishment's residue control program. Describe how it impacts the food safety system.

On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the establishment's Drug Residue Policy. The policy is as follows:

[redacted]

Drug Residue Policy:

[redacted]

[redacted]

CUSTOM EXEMPT (all species)

CE. Does the establishment conduct custom exempt slaughter operations in accordance with 9 CFR 303.1? Yes

CE1. If yes, is the establishment's custom operation being maintained and operated in accordance with sanitation requirements of 9 CFR Part 416? Yes

CE1a. Does the establishment conduct custom exempt operations before the hours it operates under inspection? Yes

CE1b. If yes, does the establishment ensure that before its employees begin working during the hours of operation under inspection, they change outer garments, clean and sanitize their hands, and clean and sanitize the facilities and equipment as set out in the establishment's Sanitation Standard Operating Procedures? Yes

CE1c. Why did you come to this conclusion in CE1, CE1a – b? Describe the observations and/or documents used to reach these decisions.

On August 17, 2010, EIAOs [redacted] and [redacted] observed the establishment employees slaughter two (2) custom exempt cows before cattle for inspection were slaughtered. The establishment employees sanitized their equipment, aprons, and utensils in accordance with their SSOP. The establishment also slaughters custom exempt cattle after cattle for inspection has been slaughtered.

CE2. Are animals intended for custom exempt slaughter segregated from animals designated for inspected slaughter? Yes

CE2a. Is separation (either physical or time) maintained between slaughter performed under inspection and slaughter performed under custom exemption? Yes

CE2b. Is separation (either physical or time) maintained between processing performed under inspection and processing performed under custom exemption? Yes

CE2c. Why did you come to this conclusion in CE2, CE2a and CE2b? Describe the observations and/or documents used to reach these decisions.

Upon arrival at the establishment, the custom exempt animals are put into a separate gated area of the pen and either slaughtered before or after FSIS inspected product. EIAOs [redacted] and [redacted] observed on August 9, 11, 13, and 17, 2010, that the custom exempt animals were put into a separate gated area of the pen from the FSIS

inspected animals. On August 17, 2010, EIAOs [redacted] and [redacted] observed the establishment employees slaughter two (2) custom exempt cows before cattle for inspection were slaughtered. The establishment employees sanitized their equipment, aprons, and utensils in accordance with their SSOP. The establishment also slaughters custom exempt cattle after cattle for inspection has been slaughtered.

CE3. Does the establishment accept field slaughtered or farm-dressed carcasses or parts for custom processing? No

CE3a. If yes, are the field slaughtered or farm-dressed carcasses or parts delivered in a sanitary manner; ready for cutting up or processing; clearly marked "Not For Sale" upon entering any part of the facility; and certified, in writing, as ambulatory at the time of slaughter by the owner of the animal? N/A

CE3b. Why did you come to this conclusion in CE3 and CE3a? Describe the observations and/or documents used to reach these decisions.

The establishment does not accept field slaughtered or farm-dressed carcasses or parts.

CE4. Are all carcasses and parts from custom slaughter or processing clearly marked as "Not for Sale" and does the establishment maintains a separation of these carcasses and parts from those carcasses and parts produced under inspection? Yes

CE4a. Does the establishment pack custom exempt product with inspected product? Yes

If yes, is it properly wrapped and labeled, does it identify all product and does the establishment ensure that the shipping container of the custom exempt product does not contain an official inspection legend? Yes

CE4b. Why did you come to the conclusions in CE4 and CE4a? Describe the observations and/or documents used to reach the decision.

The establishment will label the custom exempt product as "Not for Sale." EIAOs [redacted] and [redacted] observed on August 17, 2010, the establishment slaughtered two (2) cows for custom exempt. The two (2) custom exempt cows were kept separate from FSIS inspected cows.

CE5. Recordkeeping and Documentation: Does the establishment maintain records that document the:

- Number and kinds of custom livestock slaughtered? Yes
- Cattle that were slaughtered were ambulatory at the time of slaughter and that SRMs were properly disposed of? Yes
- Quantities and types of custom product prepared? Yes

- Names and addresses of the owners of the livestock and/or products? Yes
- Water and sewage systems are safe, as demonstrated by records from the State or local health agency? Yes
- Chemicals used in the facility are safe for the food processing environment? Yes
- Maintenance of sanitary conditions during custom operations as reflected in the Sanitation Standard Operating Procedure (SSOP) records? Yes

CE5a. Why did you come to these conclusions in CE5? Describe the observations and/or documents used to

reach the decision.

The establishment follows their SSOP and SRM program and keeps a record of all incoming livestock and the names and addresses of the owners are kept on file.

CE6. Briefly describe any additional findings (positive and negative) which were not addressed by any of the preceding questions. Include the date and results of the most recent Custom Exempt Establishment Review Report (FSIS Form 5930-1).

Pecos Valley Meats had a Custom Exempt Review on May 12, 2010. The review revealed that the establishment operates under a Sanitation Standard Operating Procedures (SSOP) plan as per 9 CFR part 416 when conducting custom exempt operations. The Consumer Safety Inspector observed the following noncompliances during the Custom Exempt Review:

Recordkeeping and Documentation: The establishment could not present any documentation for review (Letters of Guarantee) substantiating the safety of a chemical's use in a food processing environment. The establishment did not meet the regulatory requirements of 9 CFR 416.4 (c).

Maintenance of Facilities: The walls, floors, ceilings, doors, windows, and other outside openings are maintained in good repair to prevent the entrance of vermin and rodents, except for the overhead roll-up door on the inedible cooler located at the north side of the facility that has gaps around the jambs (7" x 0.5" size) and at the bottom part (a gap of 0.5") due to the fact that the door does not close tightly. The establishment covers these openings with plastic to prevent the entrance of vermin and rodents. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (b)(3).

Pest Control: In an area located on the NW corner of the premises, adjacent to the knocking area, there were three (3) old tires, scrap metal, three (3) rusty chains, and two (2) rusty fans in direct contact with the ground and a 50 gallon plastic barrel full of trash. All of these are potential homes and hiding places for rodents and other vermin that can create homes and hiding places for rodents and other vermin that can create insanitary conditions. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (a).

Marking and Labeling Custom Exempt Products and Containers: The establishment marks each individual package "Not For Sale" in letters ¼" high and placed them in a box marked "Not For Sale" in letters 3/8" high. According to what is specified in the Code of Federal Regulations (CFR), the establishment did not meet the regulatory requirements of 9 CFR 316.16.

Sewage and Waste Disposal: The establishment uses a private system (septic tanks and discharge lagoon) for the disposal of the sewage system and wastewater requiring approval by a State or local health authority. Mr. De Los Santos did not furnish to the Consumer Safety Inspector, upon request, a letter or certificate of approval from a State or local health authority. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (f).

MISCELLANEOUS (all species)

M1. Does the establishment have documented monitoring that product is maintained at 45°F or below after 24 hours of chilling? Yes

M1a. Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment keeps records of the "[redacted]. The establishment designates this as CCP-3.

M2. Has the plant had a third party audit of its food safety system? No

M2a. If yes, did the establishment implement any of the recommendations? N/A

M2b. Briefly discuss the third party audit recommendations and indicate which were implemented by the plant. N/A

M3. Does the establishment produce product under the retail exempt regulations (9 CFR 303.1(d))? No

M3a. If yes, does the establishment maintain separation of products processed as retail from products processed under inspection? N/A

M3b. Why did you come to these conclusions in M3 and M3a? Describe the observations and/or documents used to reach the decision.

The establishment does not produce product under the retail exempt regulations.

M4. Briefly describe any additional findings (positive and negative) which were not addressed by any of the preceding questions.

There are no additional findings.

M5. Analysis and Summary: Please discuss findings (positive and negative) and any regulatory noncompliances associated with HACCP 03J plans at this establishment using the relevant data gathered above. Include in your discussion how the findings impact the establishment's ability to meet the requirements of the FMIA and that impact on food safety.

Pecos Valley Meats, Est. 7299, has developed and implemented a Slaughter Meat HACCP plan which covers the Slaughter products produced at the establishment. The establishment addresses the appropriate hazards within the process, and developed controls to address each of the identified hazards. The specific pathogens of concern for this Slaughter Meat process are *E. coli* O157:H7, SRMs, and *Salmonella*. [redacted]

The establishment maintained records sufficient to document the implementation, monitoring, and maintenance of the HACCP system. The records document the monitoring of the CCPs and the critical limits. The establishment meets the requirements of the *Federal Meat Inspection Act* (FMIA) to produce a safe and wholesome product. There is no reason to believe that the establishment is producing adulterated product, which would affect public health. Observations and reviews conducted by EIAOs [redacted] and [redacted] during the course of the assessment confirmed the establishment is implementing their HACCP plan accordingly, but failed to comply with the following:

- At the steps [redacted] and put product in cooler, the establishment does not include these steps in the hazard analysis, but the steps are included in the flow diagram. Even though the establishment has failed to address this step in the Hazard Analysis, the [redacted] is a CCP (CCP-2) and is being monitored. The establishment also has supporting documentation for the [redacted] This is a noncompliance with 9 CFR 417.2 (a) (1).

- At the step of freeze variety meats, the establishment does not include this step in the hazard analysis, but this step is included in the flow diagram. Even though the establishment has failed to address this step in the Hazard Analysis, the establishment is monitoring and keeping records of the freezer temperatures. This is a noncompliance with 9 CFR 417.2 (a) (1).

- EIAOs [redacted] and [redacted] reviewed the [redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed on July 22, 2010, the QC did not indicate on the "[redacted] if the [redacted] spray was acceptable according to the HACCP plan for CCP-2. This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the [redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On July 16, 2010 and May 4, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]). This is a noncompliance with 9 CFR 417.5 (a) (3).

- EIAOs [redacted] and [redacted] reviewed the "[redacted] records for CCP-2 from May 4, 2010 through July 30, 2010. On June 11 and 16, 2010, the QC did not document on the "[redacted] for CCP-2 the [redacted]. The records only indicated that the carcasses were acceptable or ok according to the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (3).

- On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the HACCP plan for CCP-3B and observed that the establishment did not state a frequency for the thermometer calibration, but stated the [redacted]. This is a noncompliance with 9 CFR 417.5 (a) (2).

- On June 3 and 16, 2010 EIAOs [redacted] and [redacted] observed that the [redacted] CCP-1 records lacked a variety meat direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

- The establishment did not have documents supporting the monitoring procedures and frequencies listed in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

- The establishment did not have documents supporting the verification procedures and frequencies in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

- On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-3 and CCP-3B" records from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed the "[redacted] CCP-3 and CCP-3B" record dated July 17, 2010, the surface temperature documented for the variety meats (cheek meat/tongue) was 42° F. This temperature was

above the critical limit [redacted]. EIAOs [redacted] and [redacted] observed that the establishment did not take a corrective action for this deviation from a critical limit. This is a noncompliance with 9 CFR 417.3. [redacted]

- The Pre-shipment Review was being performed and documented in confirming that all CCPs were met for the production lots produced under the Slaughter HACCP plan. The reviewer however, failed to note the critical limit deviation documented on the "[redacted] CCP-3 and CCP-3B" record dated on July 17, 2010, [redacted] Moreover, the reviewer failed to take any corrective actions. This is a noncompliance with 9 CFR 417.5 (c).

EIAOs [redacted] and [redacted] recommend these deficiencies be addressed through the issuance of non-compliance reports written by in-plant inspection personnel.

Pecos Valley Meats, Est. 07299, HACCP O3C Raw, Not Ground Meat

HACCP 03C [redacted]

Which of the following products does the establishment produce under HACCP 03C?

[redacted]
Pork (answer general, custom exempt and miscellaneous questions)
Beef (answer all questions)
Other species (specify) (answer general, custom exempt and miscellaneous questions)

GENERAL

G1. List all HACCP 03C plans, products produced using those plans, CCPs, critical limits, monitoring procedures, and verification procedures associated with those plans using the template provided.

HACCP Plan	Products Produced	CCP	CL	Monitoring Procedures	Verification Procedures
O3C	Beef Trim and Beef primal Packaging	CCP-4B	[redacted]	[redacted]	[redacted]

GENERAL HAZARD ANALYSIS, FLOW DIAGRAM AND HACCP

H1. Are all hazards reasonably likely to occur identified as appropriate? Yes

H2. Are all decisions made in the Hazard Analysis supported with documentation on file? Yes

H3. Briefly explain how the answers in H1 and H2 were determined including the names of documents used.

On August 10 and 18, 2010, EIAOs [redacted] and [redacted] reviewed the O3C Hazard Analysis for Pecos Valley Meats that was in use at the time of our arrival. The establishment does not address any biological, physical or chemical hazards at any steps other than Beef Trim and Beef Primal Packaging/Variety Meat Package.

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At the receiving Carcasses step, the establishment lists biological hazards of *E. coli* O157:H7 and *Salmonella* outgrowth as well as BSE not reasonably likely to occur based on the fact that all carcasses have met all slaughter CCPs for this establishment. The establishment does not accept carcasses from other establishments. The establishment addresses outgrowth with temperature control.

- The Hazard Analysis does not include the step of Fabrication of Beef Trimmings/Beef Primals but the step is included in the Flow Diagram. This is a noncompliance with 9 CFR 417.2 (a)(1).

At the step of Beef Trim and Beef Primal Packaging/Variety Meat Package, the establishment lists biological hazards of *E. coli* O157:H7 and *Salmonella* outgrowth as reasonably likely to occur. Possible pathogen outgrowth if the temperature is not maintained at less than 44.6° F. The establishment addressed the [redacted] at CCP-4B.

At the step of Finished Product Storage (Freezer), the establishment addresses biological hazards not likely to occur based on freezer temperatures in their GMP, but does not identify the biological hazard (micro-organism) in the hazard analysis.

H4. Does the plant use a prerequisite program(s)? Yes

H4a. If yes to H4, list the names of all the prerequisite programs used as part of 03C and briefly describe the hazards each prerequisite program is preventing, monitoring procedures, and records generated.

Room Temperature Controls Program:

[redacted]

EIAOs [redacted] and [redacted] reviewed the '[redacted] records from May 4, 2010 through July 30, 2010, and observed that the establishment was maintaining the temperature of the processing room at 50° F or less. The records indicated that the establishment was monitoring and documenting the temperature of the processing room every 2 hours. EIAOs [redacted] and [redacted] also observed that the freezer temperature was monitored once per day and that the freezer temperature was maintained at or under 32° F. On August 11, 2010, EIAOs [redacted] and [redacted] observed the QC monitor the processing room temperature and the freezer temperature. The QC documented the processing room temperature and the freezer temperature on the '[redacted] record.

H4b. Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur? No

H4c. Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may affect the production of safe product. N/A

H4d. If yes to H4, with the records reviewed, has the plant had a deviation from compliance in the prerequisite program? N/A

H4e. If yes to H4d, did it constitute a trend, and did the plant reassess? N/A

H4f. Is the establishment monitoring and keeping adequate records for each of the prerequisite programs? Yes

H4g. Why did you come to the conclusions in H4d – f? Describe the observations and/or documents used to reach the decision. Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.

EIAOs [redacted] and [redacted] reviewed the '[redacted] records from May 4, 2010 through July 30, 2010, and observed that the establishment was maintaining the temperature of the processing room at 50° F or less. The records indicated that the establishment was monitoring and documenting the temperature of the processing room every 2 hours. EIAOs [redacted] and [redacted] also observed that the freezer temperature was monitored once per day and that the freezer temperature was maintained at or under 32° F. On August 11, 2010, EIAOs [redacted] and [redacted] observed the QC monitor the processing room temperature and the freezer temperature. The QC documented the processing room temperature and the freezer temperature on the '[redacted] record.

H5. Are all steps in the process(s) included in the flow diagram? Yes

H6. Briefly discuss any regulatory noncompliance associated with the flow diagram.

EIAOs [redacted] and [redacted] reviewed the flow diagram for the Raw Not Ground process and compared the flow diagram to actual product flow during Fabrication. EIAOs [redacted] and [redacted] found the flow diagram did match the actual Raw Not Ground process within the facility.

H7. Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s)? No

H7a. Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion.

Upon arrival at the establishment, EIAOs [redacted] and [redacted] reviewed the Hazard Analysis and observed that the establishment did not address the biological hazards of *E. coli* O157:H7 and *Salmonella* in the Fabrication of Beef Trimmings/Beef Primals step in the Hazard Analysis.

H8. Answer the following series of questions to determine if the design of the HACCP plan meets all requirements of 9 CFR 417.

H8a. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits? Yes

H8a1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the CCPs in the HACCP plan and confirmed that the CCPs listed the monitoring procedures and frequencies.

CCP-4B
Monitoring Procedures:

[redacted]

H8b. Are the monitoring procedures being performed as described in the HACCP plan? Yes

H8b1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-4B" from May 4, 2010 through July 30, 2010, and observed that the establishment was performing the monitoring procedures as described in the HACCP plan.

On August 19, 2010, EIAOs [redacted] and [redacted] observed the QC perform CCP-4B [redacted]. The QC documented the results on the "[redacted] CCP-4B".

H8c. Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan? Yes

H8c1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 13, 2010, EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-4B"from May 4, 2010 through July 30, 2010. EIAOs [redacted] and [redacted] observed that the establishment was performing the monitoring procedures at the frequencies specified in the HACCP plan.

H8d. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments? Yes

H8d1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the HACCP plan [redacted] for CCP-4B. For CCP-4B, the establishment stated that "[redacted]."

H8e. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions? Yes

H8e1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the CCPs in the HACCP plan listed the direct observation of monitoring activities as the following:

Pecos Valley Meats, Est. 07299, HACCP O3C [redacted]

CCP-4B:

[redacted]

H8f. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)? Yes

H8f1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and confirmed that the HACCP plan [redacted] for CCP-4B. The HACCP plan stated that "[redacted]".

H8g. Does the HACCP plan list product sampling as a verification activity? No

H8g1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] were advised by Mr. Rick De Los Santos, Plant Owner, this establishment does not list product sampling as a verification activity in the HACCP plan.

H8h. Are process-monitoring instrument calibration activities conducted as per the HACCP plan? Yes

H8h1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

[redacted]

H8i. Are direct observation verification activities conducted as per the HACCP plan? No

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H8i1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's '[redacted] CCP-4B" records. The records were reviewed from May 4, 2010 through July 30, 2010 which revealed the following:

- On July 13 and 29, 2010 EIAOs [redacted] and [redacted] observed that the "Room/Product Temperature Log CCP-4B" records lacked a direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

On August 19, 2010, EIAOs [redacted] and [redacted] observed the QC perform direct observation on the verification of the taking and recording of the product temperatures. The QC documented the direct observation results on the '[redacted] CCP-4B" records.

H8j. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment? Yes

H8j1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's '[redacted] CCP-4B" records from May 4, 2010 through July 30, 2010. The records revealed that the [redacted] as indicated in their HACCP plan.

On August 17, 2010, EIAOs [redacted] and [redacted] observed Mr. Rick De Los Santos, review the '[redacted] CCP-4B" records. Mr. De Los Santos reviewed the records in accordance with 9 CFR 417.5 (a)(3).

H8k. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP? Yes

H8k1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed that all the CCP records were designed and implemented in a manner to document the monitoring of the CCPs and critical limits. On August 13, 2010, EIAOs [redacted] and [redacted] reviewed 60 days (May 4, 2010 through July 30, 2010) of the '[redacted] CCP-4B" records and observed that the HACCP plan set out a recordkeeping system that documented the monitoring of the CCP.

H8l. Do the records contain actual values and observations obtained during monitoring? Yes

H8l1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed 60 days of records from May 4, 2010 through July 30, 2010, and observed that the '[redacted] CCP-4B" records contained actual values and observations as observed during monitoring.

H8m. Does the establishment have the supporting documentation for initial validation on file? No

H8m1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 18, 2010, Mr. Rick De Los Santos, Plant Owner informed EIAOs [redacted] and [redacted] that he does not have the supporting documentation for initial validation on file. EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-4B" records of the [redacted] HACCP plan from May 4, 2010, through July 30, 2010 and observed that the establishment continuously tested the adequacy of the procedures and limits set forth in their written HACCP plan including the review of records and are maintaining, at a minimum, the previous 60 days of validation records.

H8n. Does the establishment have the decision-making documents associated with the selection of each CCP? Yes

H8n1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's decision making documents for CCP-4B. The establishment provided EIAOs [redacted] and [redacted] with a copy of the minimum growth temperature published by Dr. [redacted], Ph D as support for the raw product temperature of less than [redacted] critical limit.

H8o. Do the documents explain why the establishment selected that location for the CCP? Yes

H8o1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The minimum growth temperature published by Dr [redacted], Ph D document is used to support the raw product temperature of less than [redacted] As cited in the scientific article, the minimum growth temperature of E. coli O157:H7 and Salmonella is [redacted] This document indicates that pathogens are more likely to grow during storage steps of the process.

H8p. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards? Yes

H8p1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

A review of the establishment's Hazard Analysis and HACCP plan revealed that the establishment has established points in their process that will prevent, eliminate, or reduce to acceptable levels the identified hazards and are identified as CCP-4B for the [redacted] HACCP plan. EIAOs [redacted] and [redacted] reviewed the establishment's supporting documents on August 16, 2010 and observed that the minimum growth temperature published by Dr. [redacted], Ph D document helped support their process.

H8q. Does the establishment have scientific, technical, or regulatory support for the critical limit? Yes

H8q1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment provided the scientific document of the minimum growth temperature published by Dr. [redacted], Ph D as support for the critical limit.

H8r. Does the support appear credible? Yes

H8r1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The minimum growth temperature scientific document published by Dr. [redacted], Ph D has been well published and recognized by FSIS for the minimum growth temperatures of various microorganisms. The microorganism of concern in this process is *E. coli* O157:H7 and *Salmonella* which has been established to have a minimum growth temperature [redacted] Based on this scientific document, the establishment set the CCP critical limit of less than [redacted]

H8s. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? No

H8s1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

- The establishment did not have documents supporting the monitoring procedures and frequencies listed in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

H8t. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done? No

H8t1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

- The establishment did not have documents supporting the verification procedures and frequencies in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

H8u. If the establishment has supporting documents for these decisions, does the documentation support the decisions? N/A

H8u1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment did not have documents supporting the monitoring and verification procedures and frequencies listed in the HACCP plan.

H8v. Do the records document the monitoring of CCPs and their critical limits? Yes

H8v1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's records from May 4, 2010 through July 30, 2010, and confirmed the establishment was documenting the monitoring of CCP-4B, and the critical limits. EIAOs [redacted] and [redacted] observed the monitoring of CCP-4B on August 19, 2010 and confirmed the establishment was properly monitoring and documenting the CCP value on the "[redacted] CCP-4B" records.

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H8w. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan? Yes

H8w1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the "[redacted] CCP-4B" records from the dates of May 4, 2010 through July 30, 2010, and confirmed that for CCP-4B, the [redacted] for CCP-4B as indicated in the HACCP plan.

H8x. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made? Yes

H8x1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the "[redacted] CCP-4B" records from the dates of May 4, 2010 through July 30, 2010, and confirmed that for CCP-4B, the [redacted] the monitoring for CCP-4B as indicated in the HACCP plan.

H8y. Are the verification procedures and results of those procedures documented? No

H8y1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 19, 2010, EIAOs [redacted] and [redacted] observed the performance of direct observation of monitoring activities, and the records review verification procedures. EIAOs [redacted] and [redacted] confirmed the establishment was documenting the direct observation of monitoring, and the records review on the "[redacted] CCP-4B" records and on the [redacted] EIAOs [redacted] and [redacted] reviewed all the CCP records from the dates of May 4, 2010, through July 30, 2010, and confirmed the establishment was documenting the performance of the direct observation of monitoring and records review verification, and documenting the results of the verification except for the following:

- On July 13 and 29, 2010 EIAOs [redacted] and [redacted] observed that the "[redacted] CCP-4B" records lacked a direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

H8z. Is the time recorded when the verification activity was performed? Yes

H8z1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the "[redacted] CCP-4B" records from the dates of May 4, 2010, through July 30, 2010, as well as observations of the verification procedures on August 19, 2010, confirmed the establishment was documenting a time that each direct observation, records review verification task was being performed.

H8aa. Does the record contain the date the record was made? Yes

H8aa1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the '[redacted] CCP-4B" records from the dates of May 4, 2010, through July 30, 2010, as well as observations of the verification procedures on August 19, 2010, confirmed the establishment was documenting the date that each record was made.

H8bb. Are the process-monitoring calibration procedures and results being recorded? Yes

H8bb1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment's HACCP plans and written calibration procedures address the [redacted]. EIAOs [redacted] and [redacted] observed the calibration of thermometers on August 17, 2010. EIAOs [redacted] and [redacted] reviewed the thermometer calibration log records from the dates of June 10, 2010, through August 6, 2010, and confirmed the establishment was documenting the results of the calibration procedures.

H8cc. Was each entry on the record made at the time the event occurred? Yes

H8cc1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the calibration of thermometers on August 17, 2010, and confirmed the establishment was documenting the calibration of the monitoring device immediately after the calibration procedures were completed.

H8dd. Does each entry include the time? Yes

H8dd1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

A review of the calibration records from the dates of June 10, 2010, through August 6, 2010, confirmed the establishment was documenting a time for each calibration procedure.

H8ee. Was each entry on the record signed or initialed by the establishment employee making the entry? Yes

H8ee1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed the calibration of thermometers on August 17, 2010, and confirmed the designated employee documented the calibration on the thermometer calibration log, and initialed the form with his initials.

H8ee. Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products? Yes

H8ee1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment maintains records for the required amount of time (1 year). Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment keeps records since 2001. On August 17, 2010, EIAOs [redacted] and [redacted] verified the Slaughter records from April 9, 2009 through April 10, 2010 were onsite.

H8ff. Are the records kept on-site for 6 months? Yes

H8ff1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The establishment maintains records for the required amount of time (1 year). Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment keeps records since 2001. On August 17, 2010, EIAOs [redacted] and [redacted] verified the Slaughter records from April 9, 2009 through April 10, 2010 were onsite.

H8gg. If the records are stored off-site after 6 months, can they be retrieved in 24 hours? Yes

H8gg1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that he has kept the Slaughter records on the property since 2001.

H8hh. Has the establishment reviewed the records associated with the production of the product, prior to shipment? Yes

H8hh1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the Pre-shipment Review Records from May 7, 2010 through August 13, 2010, and observed that the establishment reviewed the records prior to shipment.

H8ii Does the establishment list corrective actions in its HACCP plan that meet the requirements under 9 CFR 417.3? Yes

H8ii1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's HACCP plan and observed that the establishment listed corrective actions that meet the requirements under 417.3.

H8jj. Is a responsible party identified? Yes

H8jj1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP plan and observed that the establishment identifies the HACCP Coordinator as the responsible person for corrective actions.

H8kk. If corrective actions have been taken by the plant, were those corrective actions effective? Yes

H8ll. How many times within the last 60 days did the establishment have deviations from CCPs?
[redacted]imes
[redacted]-2 times
[redacted]5 times
[redacted] times

H8mm. Has a reassessment been conducted to meet the annual reassessment requirement? Yes

H8mm1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the HACCP reassessment log and confirmed the annual reassessment of the HACCP O3C [redacted] plan was performed on February 28, 2010, by Rick De Los Santos, Plant Owner to meet the annual reassessment requirements.

H8nn. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the [redacted]pes of products produced by the plant, in its analysis? Yes

H8nn1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

On August 19, 2010, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that he added a HACCP amendment dated on January 25, 2010, which indicated that the establishment would [redacted]. The amendment also stated that in the event the establishment [redacted]. On August 19, 2010, EIAOs [redacted] and [redacted] reviewed the *E. coli* O157:H7 records and observed quarterly records for March 4, 2010, April 30, 2010, and July 28, 2010. The *E. coli* O157:H7 records were all reported as negative.

H8oo. Has change occurred that could affect the hazard analysis or HACCP plan? No

H8oo1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed that the *E. coli* O157:H7 testing is not mentioned in the establishment's HACCP plan or Hazard Analysis.

H8pp. Did the establishment reassess? Yes

H8pp1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] reviewed the establishment's reassessment page and observed that the establishment reassessed on May 14, 2010.

H8qq. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately? N/A

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H8qq1. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

EIAOs [redacted] and [redacted] observed that the *E. coli* O157:H7 testing is not mentioned in the establishment's HACCP plan or Hazard Analysis.

H9. Does the execution of the HACCP plan meet all requirements of 9 CFR 417 (monitoring, verification, record keeping, corrective action, and reassessment)? No

H9a. Describe the analysis conclusions that led to your answer in H9. Describe all non-compliance finding. Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.

The written HACCP plan describes how monitoring and verification activities will be performed. It also describes the record keeping system and what records will be kept to document the results of the monitoring activities. Documents include '[redacted] CCP-4B", "[redacted]", and "[redacted]". EIAOs [redacted] and [redacted] observed that all records were being maintained and contained all required information. The execution of the [redacted] HACCP plan was observed to comply with 9 CFR 417, except for the following:

- On July 13 and 29, 2010 EIAOs [redacted] and [redacted] observed that the '[redacted] CCP-4B" records lacked a direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

- The establishment failed to [redacted] and frequencies as listed in the [redacted] HACCP plan. This is a noncompliance with 9 CFR 417.5 (a)(2).

- The establishment failed to provide decision making documents to support the [redacted] n for CCP-4B as listed in the [redacted] HACCP plan. This a noncompliance with 9 CFR 417.5 (a)(2).

G2. Does the establishment conduct its own product testing for *Salmonella* spp.? No

G2a. Does the establishment have supporting documentation filed for the sample collection procedure? N/A

G2b. Briefly describe the sample collection procedure and supporting documentation associated with the sampling procedure. Analysis: Are they being followed as written? Are there weaknesses with the procedure (frequency, test portion, fit for intended use, aseptic technique etc.) that may bring into question decisions made in the hazard analysis?

The establishment does not conduct its own product testing for *Salmonella* spp.

G2c. Does the establishment have supporting documentation filed for the microbiological testing method? N/A

G2d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Analysis: Are they being followed as written? Are there weaknesses with the method (test portion, fit for intended use, validation, sensitivity of detection, and reliability etc.) that may bring into question decisions made in the hazard analysis? N/A

G2e. Does the establishment serotype in-house positive *Salmonella* samples? N/A

G2f. Do any of the serotypes match the current CDC list of top 30 serotypes associated with common human illness? N/A

G3. Does the establishment sample and test product, equipment, or processing areas for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, *Enterobacteriaceae*)? Check all that apply

[redacted]inished product
abrication equipment (knives, steels, belts, etc.)
rocessing area
thers, please specify
No

G3a. Does the establishment have supporting documentation filed for the sample collection procedure, (i.e. locations chosen for sampling, etc.)? N/A

G3b. Briefly describe the sample collection procedure and supporting documentation associated with the sampling procedure. N/A

G3c. Does the establishment have supporting documentation filed for the microbiological testing method? N/A

G3d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. N/A

G4. Does the establishment use the microbiological data generated for decision making? N/A

G4a. Why did you come to the conclusion in G4? Describe the observations and/or documents used to reach the decision.

The establishment does not test the Raw Not Ground product for indicator organisms.

G5. Does the establishment accept returned product? No

G5a. Describe how the establishment utilizes returned product.

The establishment does not accept returned product.

G6. Does the establishment rework product? No

G6a. Describe how the plant controls the use of rework product.

The establishment does not rework product.

BEEF (Only answer if chosen Beef)

B1. Is *E. coli* O157:H7 addressed in the establishment's food safety system? Yes

B2. What program is used to control *E. coli* O157:H7 on incoming beef products? Check all that apply.

[redacted]HACCP

[redacted]Sanitation SOP
Pre-requisite Programs
Other, please specify

B3. Does the establishment produce raw ground beef components? Check all that apply.

__ No
_X_ Trim
__ Sub-primals
__ Head meat
_X_ Cheek meat
__ Weasand meat
__ Advanced Meat Recovery (AMR) product
__ Low-temperature rendered products
_X_ Other, please specify Primals

B4. Does the establishment use tenderizing methods (e.g. blades, pins, injectors etc.) on fabricated products? No.

B4a. If yes, what does the establishment use for tenderizing? Check all that apply N/A

__ Blades
__ Pins
__ Needles
__ Injection of tenderizers
__ Others, please specify

B5. Does the establishment produce 'Specially handled beef manufacturing trimmings"? No.

INTERVENTIONS AND VALIDATION for *E. coli* O157:H7

IV1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following? (Purchase specifications: a set of requirements for incoming product established by buyer and agreed to be met by the supplier before the product is purchased) If yes, check all that apply

__X No
__ Validated intervention methods during slaughter
__ Testing of carcasses for *E. coli* O157:H7
__ Temperature
__ Other, please specify:

IV1a. How are purchase specifications verified? Check all that apply.

__ Third Party audit
__ Test results from supplier
__ In-house testing
_X_ Other, please specify: The establishment does not accept carcasses from other establishments.

IV2. Does the establishment use one or more of the following cross-contamination controls? Check all that apply.

[redacted]Sanitation of knives and steels. If yes, briefly describe how this is done
establishment sanitizes their knives and steels as needed in the fabrication room.
Maintain separation of lots from different suppliers

[redacted]Only group previously tested negative for *E. coli* O157:H7 supplier lots
None of the above
Other, please specify:

IV3. Does the establishment have documented monitoring that the fabricated product surface temperature was maintained at or below 45°F during processing?

_X_ Yes
__ No
__ Other temperature, please specify:

IV4. If the establishment applies any intervention on the fabricated product, check all that apply

_X_ No intervention
__ Organic acid
__ Acidified sodium chlorite
__ Acidified calcium sulfate
__ Irradiation
__ Other, please specify:

IV4a. Is the intervention included in any of the following? Check all that apply. N/A

__ HACCP plan
__ Sanitation SOP
__ Prerequisite Program
__ GMPs
__ Other, specify

IV4b. Is the intervention adequately validated and documented? N/A

Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.

The establishment does not apply an intervention on the fabricated product.

IV4c. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? N/A

IV4d. If the critical values have been identified for the intervention, are they being applied in the HACCP plan in a similar manner? N/A

IV4e. Is the product or product formulation referred to in the documented validation the same as or similar to the product or product formulation for which the establishment is using the intervention? N/A

IV4f. Is the establishment using the intervention as described in the validation with regards to equipment and procedures? N/A

IV4g. If the critical variables, product formulation, procedure or equipment used by the establishment are *not* the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? N/A

IV4h. If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? N/A

IV4i. Did the establishment test for the adequacy of the intervention to reduce *E. coli* O157:H7? N/A

IV4j. Does the establishment have a rational basis or data to show that the reduction of *E. coli* O157:H7 by the intervention is sufficient to control the level of contamination of *E. coli* O157:H7 that may be present on incoming products? N/A

IV5. Why did you come to the conclusions in IV4a – j? Describe the observations and/or documents used to reach the decision. Further describe interventions the establishment has in place addressing *E. coli* O157:H7.

The establishment does not apply an intervention on the fabricated product.

SAMPLING AND TESTING

ST1. Does the establishment sample incoming carcasses for *E. coli* O157:H7? No

ST1a. Does the establishment have supporting documentation filed for the sample collection procedure? N/A

ST1b. Briefly describe the sample collection procedure and supporting documentation associated with the carcass sampling procedure. Analysis: Are they being followed as written? Are there weaknesses with the procedure (frequency, test portion, fit for intended use, aseptic technique, etc.) that may bring into question decisions made in the hazard analysis? N/A

ST1c. Does the establishment have supporting documentation filed for the microbiological testing method? N/A

ST1d. Briefly describe the microbiological method and supporting documentation associated with the microbiological testing method. Analysis: Are they being followed as written? Are there weaknesses with the method (test portion, fit for intended use, validation, sensitivity of detection, and reliability) that may bring into question decisions made in the hazard analysis? N/A

ST1e. Using the FSIS method for comparison: is the sample collection procedure and testing method used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination present on the carcass, i.e. is this procedure as sensitive as the FSIS method? N/A

ST1f. Why did you come to the conclusion in ST1e? Describe the observations and/or documents used to reach the decision. N/A

ST2. Has the establishment ever had a carcass sample test positive for *E. coli* O157:H7? N/A

ST3. Does the establishment have corrective action procedures in place when a carcass is positive for *E. coli* O157:H7? N/A

ST3a. Describe the corrective action procedures. N/A

ST4. Does the establishment sample fabricated product (can include both raw ground beef components and non-raw ground beef components) for *E. coli* O157:H7? Check all that apply

__ Yes – all product
_X_ Yes - if destined for raw ground beef production
__ Yes – if required to by customers
__ No
__ Other

ST4a. Is sampling for *E. coli* O157:H7 included in any of the following? Check all that apply.
__ HACCP plan
__ Sanitation SOP
__ Prerequisite Program
__ GMPs
_X_ Other, specify, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that he does not have the procedures for the *E. coli* O157:H7 sampling. Mr. De Los Santos informed EIAOs [redacted] and [redacted] that he collects samples the same way as FSIS does when sampling for *E. coli* O157:H7.

ST4b. Is fabricated-product testing for *E. coli* O157:H7 included in the HACCP plan, is it a CCP? No

ST4c. Does the establishment have supporting documentation filed for the sampling procedure? No

ST4d. Briefly describe the sample collection method and supporting documentation. Is the procedure being followed as written? Analysis: Are they being followed as written? Are there weaknesses with the procedure (frequency, test portion, fit for intended use, aseptic technique, etc.) that may bring into question decisions made in the hazard analysis?

- Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that the establishment does not have written sample collection procedures. This is a noncompliance defined under 9 CFR 417.5 (a) (1).

ST4e. Does the establishment have supporting documentation filed for the microbiological testing procedure? No

ST4f. Briefly describe the microbiological method and supporting documentation filed associated with the testing procedure. Analysis: Are they being followed as written? Are there weaknesses with the method (test portion, fit for intended use, validation, sensitivity of detection, and reliability etc.) that may bring into question decisions made in the hazard analysis?

- The establishment could not provide any written procedures as to how they will collect the boneless beef trim to ensure the detection of *E. coli* O157:H7 is suitable for the type of product manufactured. Further, the firm does not have written support for their laboratory analytical testing methodology. This is a noncompliance with 9 CFR 417.5 (a) (1).

ST4g. Using the FSIS method for comparison: is the sample collection procedure and testing method used by the establishment adequate to detect low levels of *E. coli* O157:H7 contamination in every lot, i.e. is this procedure as sensitive as the FSIS method? N/A

ST4h. Describe how you came to your conclusion in ST4g.

On August 19, 2010, Mr. Rick De Los Santos, Plant Owner informed EIAOs [redacted] and [redacted] that he does not have the testing procedures for the *E. coli* O157:H7 sampling that is done at his establishment. Mr. De Los Santos informed EIAOs [redacted] and [redacted] that he collects samples the same way as FSIS does when sampling for

E. coli O157:H7. Mr. De Los Santos informed EIAOs [redacted] and [redacted] that he does not have the supporting documentation filed for the microbiological testing procedure. Mr. Santos informed EIAOs [redacted] and [redacted] that his customers request COAs from his establishment and that is why he is performing the *E. coli* O157:H7 sampling. Mr. De Los Santos also mentioned that he performs the *E. coli* O157:H7 sampling as a verification to see if the intervention in the Slaughter process ([redacted] is effective.

ST5. Does the establishment hold the sampled lot of fabricated product pending test results? Yes

ST6. Has the establishment ever had a sample test positive for *E. coli* O157:H7 from its own testing of fabricated product? No

ST6a. The establishment has had __0__ positives out of __4__ samples in the last 6 months.

ST7. Has the establishment had a sample test positive for *E. coli* O157:H7 from FSIS testing of fabricated-product in the last 12 months? No

ST8. Does the establishment have corrective action procedures in place when a fabricated product is positive for *E. coli* O157:H7? No

ST8a. Briefly describe the corrective action procedures, adequacy, and history of implementation. N/A

ST9. Has the establishment ever been implicated by FSIS as supplier to a lot of raw ground beef that tested positive for *E. coli* O157 and/or was associated with a recall? No

ST9a. Briefly describe the outcome of these findings. Was any regulatory action taken at this establishment? N/A

CUSTOM EXEMPT (all species)

CE. Does the establishment conduct custom exempt processing operations in accordance with 9 CFR 303.1? Yes

CE1. If yes, is the establishment's custom exempt operation being maintained and operated in accordance with sanitation requirements of 9 CFR Part 416? Yes

CE1a. Does the establishment conduct custom exempt operations before the hours it operates under inspection? Yes

CE1b. If yes, does the establishment ensure that before its employees begin working during the hours of operation under inspection, they change outer garments, clean and sanitize their hands, and clean and sanitize the facilities and equipment as set out in the establishment's Sanitation Standard Operating Procedures? Yes

CE1c. Why did you come to this conclusion in CE1, CE1a – b? Describe the observations and/or documents used to reach these decisions.

Throughout the course of the comprehensive food safety assessment, EIAOs [redacted] and [redacted] did not observe custom exempt processing in the raw not ground processing room.

CE2. Is separation (either physical or time) maintained between processing performed under inspection and processing performed under custom exemption? Yes

CE2a. Why did you come to this conclusion in CE2? Describe the observations and/or documents used to reach these decisions.

EIAOs [redacted] and [redacted] observed custom exempt carcasses in the cooler identified by a tag on carcass that has the name of the owner, the date of slaughter, the ear/back tag number, and the establishment will hold the carcass for 10 days only.

CE3. Are all products produced from custom processing clearly marked as "Not For Sale" and does the establishment maintain a separation of these products from those produced under inspection? Yes

CE3a. Does the establishment pack custom exempt product with inspected product? Yes

If yes, is it properly wrapped and labeled, does it identify all product and does the establishment ensure that the shipping container of the custom exempt product does not contain an official inspection legend? Yes

CE3b. Why did you come to the conclusions in CE3 and CE3a? Describe the observations and/or documents used to reach the decision.

Throughout the course of the comprehensive food safety assessment, EIAOs [redacted] and [redacted] did not observe custom exempt processing in the raw not ground processing room.

CE4. Briefly describe any additional findings (positive and negative) which were not addressed by any of the preceding questions. Include the date and results of the most recent Custom Exempt Establishment Review Report (FSIS Form 5930-1).

Pecos Valley Meats had a Custom Exempt Review on May 12, 2010. The review revealed that the establishment operates under a Sanitation Standard Operating Procedures (SSOP) plan as per 9 CFR part 416 when conducting custom exempt operations. The Consumer Safety Inspector observed the following noncompliances during the Custom Exempt Review:

Recordkeeping and Documentation: The establishment could not present any documentation for review (Letters of Guarantee) substantiating the safety of a chemical's use in a food processing environment. The establishment did not meet the regulatory requirements of 9 CFR 416.4 (c).

Maintenance of Facilities: The walls, floors, ceilings, doors, windows, and other outside openings are maintained in good repair to prevent the entrance of vermin and rodents, except for the overhead roll-up door on the inedible cooler located at the north side of the facility that has gaps around the jambs (7" x 0.5" size) and at the bottom part (a gap of 0.5") due to the fact that the door does not close tightly. The establishment covers these openings with plastic to prevent the entrance of vermin and rodents. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (b)(3).

Pest Control: In an area located on the NW corner of the premises, adjacent to the knocking area, there were three (3) old tires, scrap metal, three (3) rusty chains, and two (2) rusty fans in direct contact with the ground and a 50 gallon plastic barrel full of trash. All of these are potential homes and hiding places for rodents and other vermin that can create homes and hiding places for rodents and other vermin that can create insanitary conditions. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (a).

Marking and Labeling Custom Exempt Products and Containers: The establishment marks each individual package "Not For Sale" in letters ¼" high and placed them in a box marked "Not For Sale" in letters 3/8" high. According to what is specified in the Code of Federal Regulations (CFR), the establishment did not meet the regulatory requirements of 9 CFR 316.16.

Sewage and Waste Disposal: The establishment uses a private system (septic tanks and discharge lagoon) for the disposal of the sewage system and wastewater requiring approval by a State or local health authority. Mr. De Los Santos did not furnish to the Consumer Safety Inspector, upon request, a letter or certificate of approval from a State or local health authority. The establishment did not meet the regulatory requirements of 9 CFR 416.2 (f).

MISCELLANEOUS

M1. How does the establishment define a lot?

__ Based on 5 combo bins
__ Based on combo bins from one supplier
__ Based on combo bins from suppliers that use validated intervention methods
__ All combo bins received in one day
__ Clean up to clean up
__ Period of time
_X_ Other, please specify, Mr. Rick De Los Santos, Plant Owner, informed EIAOs [redacted] and [redacted] that every test sampled for *E. coli* O157:H7 is considered a lot because the establishment was not slaughtering/processing regularly.

M2. How many outside suppliers of carcasses and/or boxed beef has the establishment used in the last 30 days? Check all that apply

_X_ Only from its own slaughter plant
__ 1 (other slaughter plant)
__ 2-3
__ 4-6
__ > 6

M3. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

__ After processing carcasses from a supplier
__ After processing carcasses from a group of suppliers
__ After each shift
_X_ Daily after production
__ Less than daily (extended clean up)
__ Other, please specify

M4. Does the establishment receive carcasses from cattle 30 months of age or older containing vertebral columns or other specified risk materials? No

M4a. If yes, describe the procedure the establishment uses to maintain the identity of the carcasses 30 months of age or older and the procedure for removal of the SRMs. N/A

M5. Has the establishment had a third party audit of its food safety system? No

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M5a. If yes, were any of the recommendations implemented? N/A

M5b. Briefly discuss the third party audit recommendations and indicate which were implemented by the establishment. N/A

M6. Does the establishment produce product under the retail exempt regulations (9 CFR 303.1(d))? No

M6a. If yes, does the establishment maintain separation of products processed as retail from products processed under inspection? N/A

M6b. Why did you come to these conclusions in M6 and M6a? Describe the observations and/or documents used to reach the decision.

The establishment does not produce product under the retail exempt regulations (9 CFR 303.1 (d)).

M7. Briefly describe any additional findings which were not addressed by any of the proceeding questions.

There was no additional findings.

M8. Analysis and Summary: Please discuss findings (positive and negative) and any regulatory noncompliances associated with HACCP 03C Meat plans at this establishment using the relevant data gathered above. Include in your discussion how the findings impact the establishment's ability to meet the requirements of the FMIA and that impact on food safety.

Pecos Valley Meats, Est. 7299, has developed and implemented a [redacted] HACCP plan which cover the [redacted] products produced at the establishment. The establishment addresses the appropriate hazards within the process, and developed controls to address each of the identified hazards. The specific pathogens of concern for this [redacted] process are *E. coli* O157:H7 and *Salmonella*. The establishment has controls in place to address these specific pathogens.

The establishment maintained records sufficient to document the implementation, monitoring, and maintenance of the HACCP system. The records document the monitoring of the CCPs and the critical limits. The

establishment meets the requirements of the *Federal Meat Inspection Act* (FMIA) to produce a safe and wholesome product. There is no reason to believe that the establishment is producing adulterated product, which would affect public health. Observations and reviews conducted by EIAOs [redacted] and [redacted] during the course of the assessment confirmed the establishment is implementing their HACCP plan accordingly, but failed to comply with the following:

- The Hazard Analysis does not include the step of Fabrication of Beef Trimmings/Beef Primals but the step is included in the Flow Diagram. This is a noncompliance with 9 CFR 417.2 (a)(1).

- On July 13 and 29, 2010 EIAOs [redacted] and [redacted] observed that the "[redacted] CCP-4B" records lacked a direct observation verification for those weeks. This is a noncompliance with 9 CFR 417.4 (a) (2)(ii).

- The establishment did not have documents supporting the monitoring procedures and frequencies listed in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

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- The establishment did not have documents supporting the verification procedures and frequencies in the HACCP plan. This is a noncompliance with 9 CFR 417.5 (a) (2).

- The establishment could not provide any written procedures as to how they will collect the boneless beef trim to ensure the detection of E. coli O157:H7 is suitable for the type of product manufactured. Further, the firm does not have written support for their laboratory analytical testing methodology. This is a noncompliance with 9 CFR 417.5 (a) (1).

EIAOs[redacted] and[redacted] recommends these deficiencies be addressed through the issuance of non-compliance reports written by in-plant inspection personnel.