Food Safety Record Keeping For The Dairy Industry Under FSMA
Webinar presented on 7-30-2014

Today's Presenters




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Presentation materials available at: **www.usdairy.com/foodsafety**

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Food Safety Record Keeping For The Dairy Industry Under FSMA

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FSMA Overview

- Signed into law on Jan 4, 2011
- Most sweeping food safety legislation in over 70 years.
- Legislative mandate for FDA to require comprehensive science based preventive controls across the entire food supply
- It covers manufacturing, packaging, holding and transportation of food.
- Webinar will focus on Recordkeeping related to Preventive Controls proposed rule and Traceability

FDA Consumer Health Information

Food Bill Aims to Improve Safety

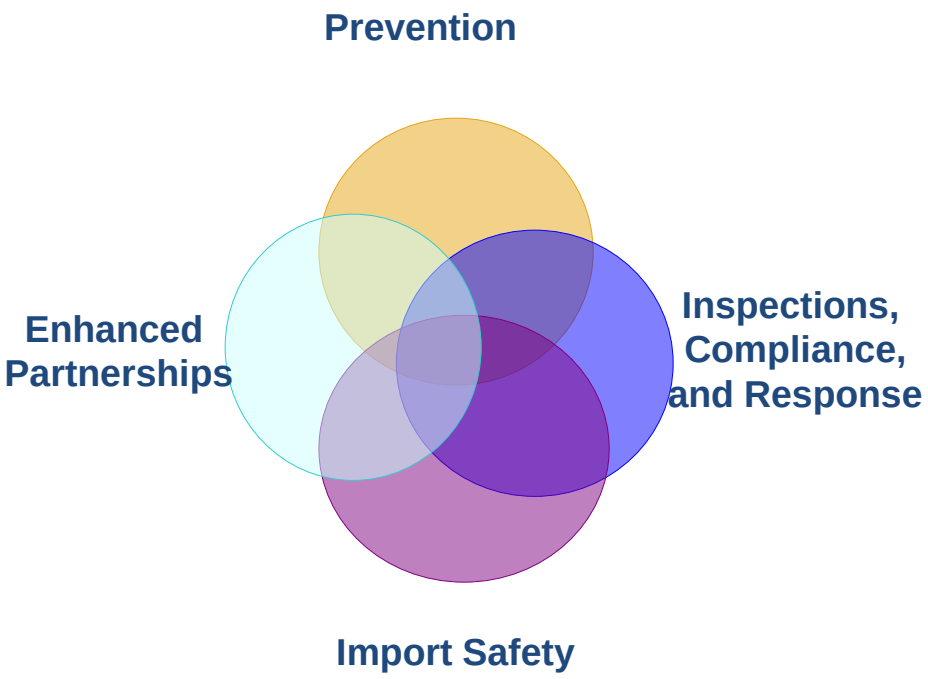
Recent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The reasoning is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

Under the provisions of FSMA, companies will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected

Key FSMA Provisions And Industry Impact



Implications for Industry

- New Responsibilities on Food Companies
- Expanded FDA Enforcement Power
- Controls on Imports
- Greater information sharing among FDA, State, Local agencies

Proposed Rules & New Food Company Responsibilities

Hazard Analysis and
Risk Based Preventive Controls

- Produce Safety
- Preventive Controls for Human food
- Preventive Controls for Animal Food
- Foreign Supplier Verification
- 3rd Party Auditor Accreditation for Foreign Facilities
- Intentional Adulteration
- Sanitary Transportation

Changes FSMA brings

- Requires a Food Safety Plan
  - Preventive controls and Recall Plan
  - Defined Records to determine compliance
- Expands FDA's Routine Inspectional Records Access
  - Food Safety Plan, Hazard Analysis, Preventive Controls, Monitoring SOPs, Corrective Action SOPs, Verification SOPs, Recall Plan, and all associated records
- Expands FDA's Non-Routine Authority
  - Expanded from authority provided by the Bioterrorism Act of 2002
  - In a SAHCODHA event (serious adverse health consequences or death to humans or animals), FDA has expanded access to records and has legal access to view and copy records
  - Need "reasonable probability"
- Potential future inclusions in final rule
  - Environmental and finished product testing
  - Customer/consumer complaints related to food safety
  - Monitoring of supply chain (supplier verification)
  - Traceability

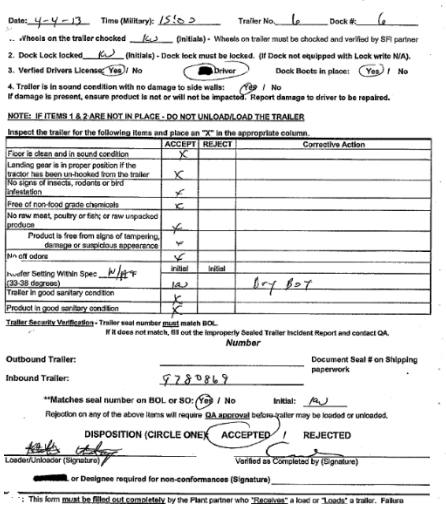
FDA FOOD SAFETY MODERNIZATION ACT

Types of Records

- Companies maintains records of various activities
- Required by customers
  - Internal Audits, Quality and Compliance, Shipping Temperatures
- Required by regulatory agencies
  - PMO
  - Mandatory HACCP for juice or seafood
  - Bioterrorism traceability requirements
- Required for support of Food Safety and Quality
  - Separate Food Safety from other records
- Focus of today is **Food Safety** records
  - Best Practices apply to all record types
  - Records are your way of showing customers and regulators that you know what you are doing and are producing safe products

Good Records are believable!

- Records must “tell the story” of what happened at some point in the past
  - If it isn’t documented, it did not happen!
- They must be a truthful and accurate account of events
  - If it is documented, it happened exactly that way
  - Records created in real time are more believable
- It is no sin for stuff to happen; but it is a sin to not ‘document and correct’ and ‘document the correction’



Date: 4-4-13 Time (Military): 1502 Trailer No. 6 Dock #: 6

1. Wheels on the trailer chocked KJ (initials) - Wheels on trailer must be chocked and verified by SPI partner
2. Dock Lock locked KJ (initials) - Dock lock must be locked. (If Dock not equipped with Lock write N/A).
3. Verified Drivers License: (Yes) / No Driver Dock Boots in place: (Yes) / No
4. Trailer is in sound condition with no damage to side walls: (Yes) / No
If damage is present, ensure product is not or will not be impacted. Report damage to driver to be repaired.

NOTE: IF ITEMS 1 & 2 ARE NOT IN PLACE - DO NOT UNLOAD/LOAD THE TRAILER

Inspect the trailer for the following items and place an "X" in the appropriate column.

	ACCEPT	REJECT	Corrective Action
Floor is clean and in sound condition	X		
Landing gear is in proper position if the tractor has been un-hooked from the trailer	X		
No signs of insects, rodents or bird infestation	X		
Free of non-food grade chemicals	X		
No raw meat, poultry or fish; or raw unpacked produce	X		
Product is free from signs of tampering, damage or suspicious appearance	X		
No off odors	X		
Trailer Setting Within Spec 34°F (33-38 degrees)	initial KJ	initial	Dry Box
Trailer in good sanitary condition	X		
Product in good sanitary condition	X		

Trailer Security Verification - Trailer seal number must match BOL.
If it does not match, fill out the Improperly Sealed Trailer Incident Report and contact QA.

Outbound Trailer: Number
Inbound Trailer: 7788869 Document Seal # on Shipping paperwork

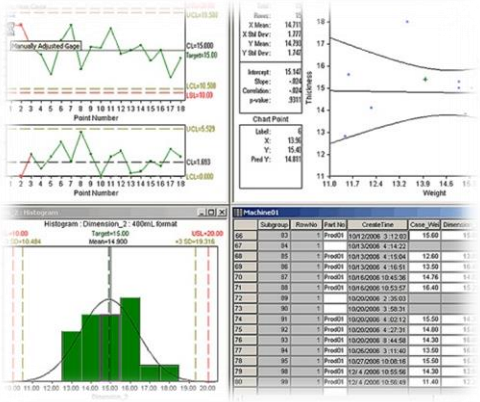
**Matches seal number on BOL or SO: (Yes) / No Initial: KJ
Rejection on any of the above items will require QA approval before trailer may be loaded or unloaded.

DISPOSITION (CIRCLE ONE) ACCEPTED / REJECTED

Loader/Unloader (Signature) Verified as Completed by (Signature)

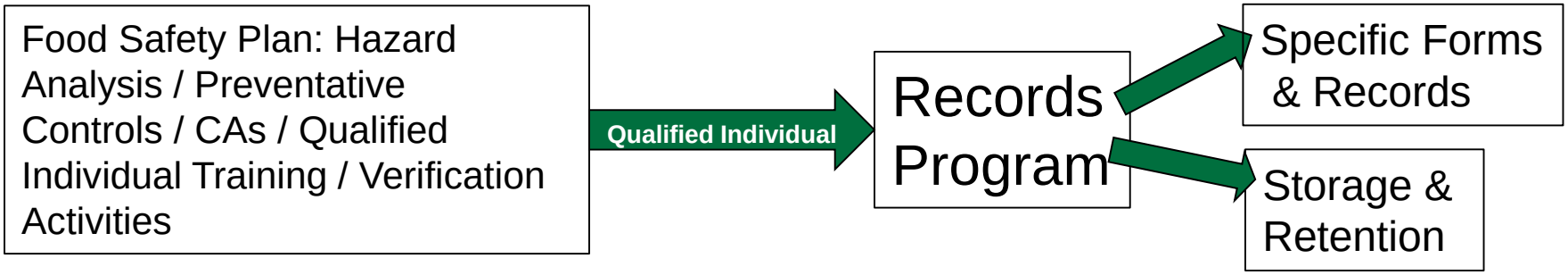
[redacted] or Designee required for non-conformances (Signature)

*: This form must be filled out completely by the Plant partner who "Receives" a load or "Loads" a trailer. Failure



Practices & Requirements

Steps of a Good Record Keeping Program



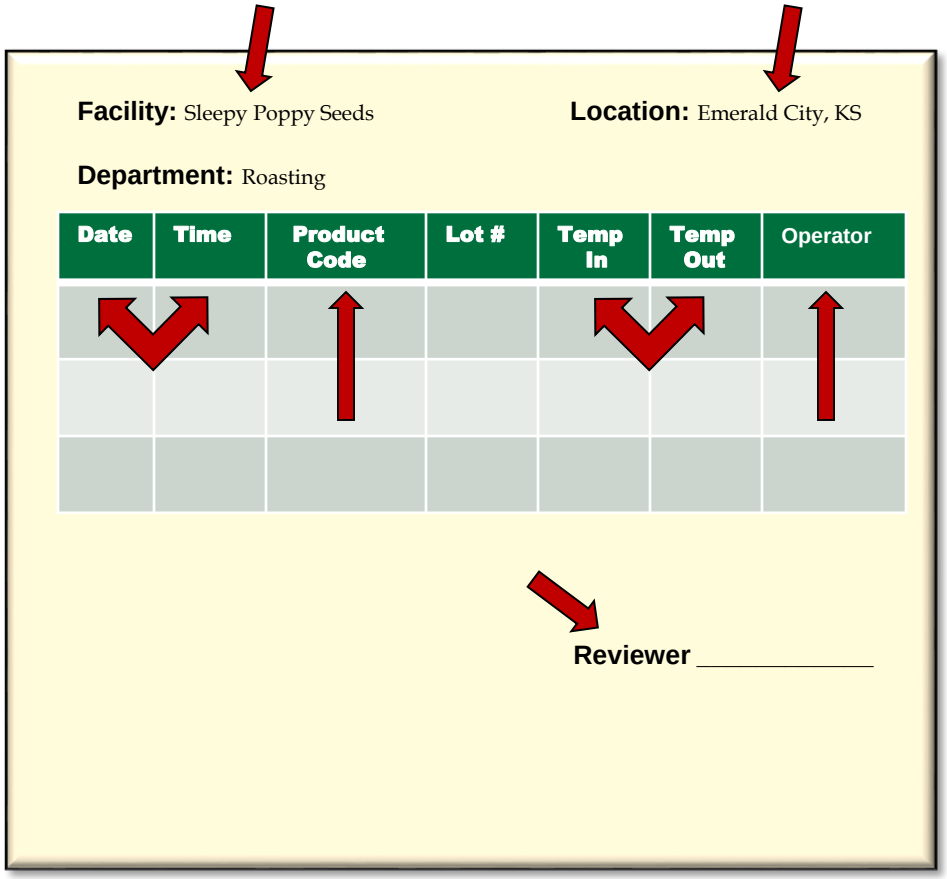
- Design the Program
  - Based on the Food Safety Plan requirements
  - Food Safety Portions developed by Qualified Individual(s)
  - Data collection points and forms based on Preventative Controls (PCs)
  - Data Access – Roles & Security
- Designing Individual Forms and Data Acquisition
- Recording Information / Completing Forms
- Record Corrective Actions Taken (or rationale for non-action)
- Record Review and Approval
- Storage & Retention

FSMA General Requirements of Records (117.305)

- Original records, true copies or electronic records
- Contain actual Values and Observations
- Accurate, indelible, and legible
  - Facts, not opinions
- Created concurrently with the activity
  - In real time
  - Not ahead of time
  - Not significantly after the event
- Detailed as necessary to provide history of work performed

Every Record has Required Information

- Facility Name & Location (does not need to be full address)*
- Department, Equipment or Process Point
- Date and Time of observation/activity*
- Critical Limits*
- Product Name/Code, where appropriate*
- Manufacturing Lot ID
- Actual Observation/Data Collection*
- Signature/Initials of the recorder*
- Signature/Initials of reviewer (s)*



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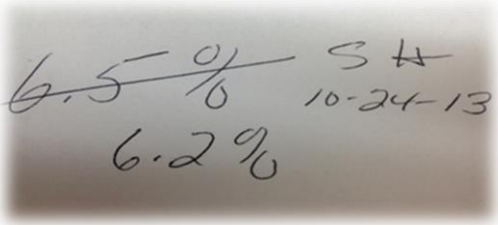
** Explicitly Required by FSMA*

What if I make a mistake on a record?

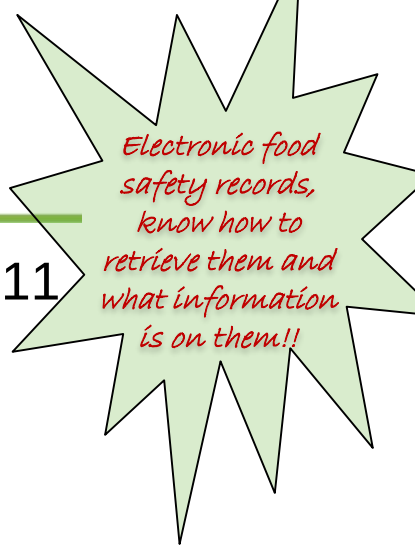
- Know how to correct mistakes and change records
  - Single line through the mistake
  - Document correct value
  - Initial and date



- Have a procedure in place
  - What types of mistakes can be corrected
  - Who can correct them
  - Use of abbreviations, blank spaces, or arrows up/down
  - When mistakes must be corrected

    Example—only the employee who made the mistake can correct the mistake

Electronic Records



- For FSMA, electronic records must comply with 21 CFR 11
- Valid
- Traceable
- Recommend segregation for audit purposes
- Electronic data collection and retention best practices (see PMO appendix H)
  - ✓ Data shall provide a reasonable account of the process being recorded
  - ✓ Write Once, Read Many (WORM)
  - ✓ Verified visually for accuracy
  - ✓ Identify any changes or updates
  - ✓ Back up data at least once every twenty-four hours
  - ✓ Uninterruptible Power Supply capable of maintaining power
  - ✓ Provide an anomalies report indicating any system or communication failure
  - ✓ A written user's guide

Requirements of Records Review 117.150(d)(2)

- Records Reviewed by (or under the oversight of) a qualified individual
  - Ensure that records are complete
  - The activities reflected in the records occurred in accordance with the Food Safety Plan (FSP)
  - The PCs are effective
  - Appropriate decisions were made about corrective actions
- Records Reviewed within the following time frames
  - ‘Records of monitoring’ and ‘Corrective action’ records within a week after records are made
  - Records of calibration within a reasonable time after the records are made

Retention Requirements

Proposed FSMA Rules Specifically Require

- Food Safety Plans must always be kept on-site
- 2 year retention of food safety records
- 6 months on-site storage
- 24 hour retrieval if stored off-site after 6 months
- Electronic or paper records are acceptable

Record Retention Best Practices

- Know your company's retention requirements
- Follow your company's retention requirements

Best Practices for completing a record

- Record facts only
  - Complete information
  - No opinions
- Avoid embellishment
  - No excess adjectives
  - Comments that could be misinterpreted
- Narrative essentials
  - What was done or not done and why
  - Why actions were or weren't taken
  - Corrective actions taken

Other Documentation – The same principles apply

- Other Records should follow the same guidelines
- Audit / Inspection Reports
  - Findings should record observable facts, not opinions or speculation
  - Findings should be followed up with corrections
- E-Mails
  - Follow good email etiquette
  - Base opinions provided on sound logic and facts
  - Avoid sarcasm and humor
  - Avoid commenting on areas outside your area of expertise
- Pictures
  - Follow your company's policy to determine when allowed
  - Make sure picture captures issue being addressed and not extraneous background
  - When possible, take pictures after correction has been made
  - Have system in place to manage pictures

Records Types and Examples

Typical Food Safety Records

- Batch / Lot records
- Pasteurizer
  - Temperature/Timing/Sealing
  - Routine Operator Checks
- Charts
  - PC (or CCP) Critical Limit Validations
  - Process and Storage Time/Temperature
  - Metal Detector
  - Sanitation -- CIP/COP/Manual Clean
  - Traceability
- Calibration of process monitoring and verification instruments
  - pH and Salt Calibrations
  - Autoclave Records
  - Negative/Positive Controls
- Corrective Action Logs

Organizing your records - Have a system and tools

- Identify and categorize your forms
  - Food safety related, quality only, maintenance,…
- Ensure that food safety forms meet FSMA requirements
  - Consider color coding
- Consider creating a menu of records to share with inspectors
  - Helps identify who needs to be trained
  - Prevents confusion during an audit

Example Tool– “Who keeps records”

Process Flow Steps

Design/ Pre-Production	Receiving/ Storage	Batching	Processing	Packaging	Finished Product	Post Ship

Plant Wide Programs

Corporate Programs

Example Tool– "Who keeps records"

Design/ Pre-Production	Receiving/ Storage	Batching	Processing	Packaging	Finished Product	Post Ship
Corp QA Risk Assessment Hazard analysis HACCP plan Transit / warehouse requirements Supplier/Corp Quality Approved supplier list / audits results Required tests / COA's Raw Material Specs Packaging specs R&D Ingredient sensitivity class Formulas Designed Safety Hurdles (aW, pH..) Packaging Shelf life validation	Dock Personnel Seal integrity Temp validation product & truck COAs/papers from vendor Time/date/lot #'s tracking Proper storage conditions Plant QA COA's On-site analytical tests Corrective Actions (narrative)	Operators/ Supervisors Formula/Quantities Product/Batch # Lot #'s Batch/WIP tracking CCP records - Critical ingredient - Temperatures - Allergen x-contamination control Corrective actions (narrative) Plant QA Procedures Traceability CCP sheets Allergen control	Operators/ Supervisors Time/temp CCP data Batch Sheets Corrective action logs (Narrative) QA Calibration records At-line analytical	Operators/ Supervisors Label matching Case code matching Proper packaging Seal integrity Lot tracking Time/temp CCP's	Plant QA Finished product testing Warehouse time/temp Traceability Tampering control Hold procedures / log sheets & why released Destruction / disposition logs & why Qualified Individual Final verification Sign-off on shipped product	Corp QA Controls/Audits - Transit companies - Warehouses - Customer Logistics Tracking

Plant Wide Programs, Activities, Documents
Quality: Laboratory calibration, testing methodologies
Engineering/Maintenance: process controls, calibrations, foreign material control, FSOP's, vendor/maintenance control, equipment design, validation of air quality/flow, filters, water quality,…
Sanitation: Master sanitation plan, SSOP's, swabbing plans, max run times, logs validating plan followed
HR/Plant: GMP procedures & training

Corporate Level Programs, Activities, Documents
Food Safety/Quality/Legal: Risk Assessment Hazard analysis, Recall Plan, Qualified Individuals List, FS plan/HARPC reviews
Engineering: Plant Design, People/RM flow, air flow, clean rooms, overpressures, water/air treatment,…
Procurement: Supplier verification

Example Records

Do not leave blanks

MAKE ROOM RECORD **DATE:** **7-Oct-2013**

VAT #	1	2	3	4	5	6
OO VAT # USED	1	2	3	4	1	2
OPERATOR INITIALS	JAM	JAM	JAM	JAM	JAM	JAM
CHEESE TYPE *	ROMANO	ROMANO	ROMANO	ROMANO	ROMANO	ROMANO
PROGRAM *	5	5	5	5	5	5
LOT SIZE *	48000 LB	48000 LB	48000 LB	48000 LB	48000 LB	48000 LB
AGITATOR INSPECTION	OK	OK	OK	OK	OK	OK
HOSE & VALVE SANITIZED	YES	YES	YES	YES	YES	YES
TOOLS ACCOUNTED FOR:	YES	YES	YES	YES	YES	YES
CIP INSPECTION	OK	OK	OK	OK	OK	OK
ACTUAL FILL TIME	6:00 AM	6:42 AM	7:23 AM	8:06 AM	8:48 AM	9:30 AM
INGREDIENT TYPE	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
AMOUNT	1 bag	1 bag	1 bag	1 bag	1 bag	1 bag
LOT #	1102112476	1102112476	1102112476	1102112476	1102112476	1102112476
INGREDIENT TYPE	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
AMOUNT	1 bag	1 bag	1 bag	1 bag	1 bag	1 bag
LOT #	4112113796	4112113796	4112113796	4112113796	4112113796	4112113796
INGREDIENT TYPE	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
AMOUNT	1 bag(60oz)	1 bag(60oz)	1 bag(60oz)	1 bag(60oz)	1 bag(60oz)	1 bag(60oz)
LOT #	862596	862596	862596	862596	862596	862596
INGREDIENT TYPE	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
AMOUNT	2 bags(32oz)	2 bags(32oz)	2 bags(32oz)	2 bags(32oz)	2 bags(32oz)	2 bags(32oz)
LOT #	869080	869080	869080	869080	869080	869080
LBS OF STARTER BLEND	350	350	350	350	350	350
STARTER LOT #	13100601	13100601	13100601	13100601	13100601	13100601
RENNET TYPE *	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX	XXXXX
TIME RENNET ADDED	6:45 AM	7:25 AM	8:10 AM	8:50 AM	9:30 AM	10:15 AM
OZ OF RENNET USED *	55 oz	55 oz	55 oz	55 oz	55 oz	55 oz
MILK SILO #	4	4	4	4	4	4
Milk Type *	B	B	B	B	B	B
SKIM SILO #	2	2	2	2	2	2
Milk Type *	B	B	B	B	B	B
CREAM SILO #						
Milk Type *						
COMMENT						

AR

*DO NOT USE THE COLORED RED IN THE MAKESHEETS

SUPERVISOR_____

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Include operating range on document

CHEESE PLANT CIP DAILY CHECK

Recommended Concentrations

	Caustic Req.	Chlorine Req.	Nitric Acid 30% Req.	Sanitizer Req.	RECORD ONE CIRCUIT EACH DAY
Vats - Short	0	0	4 - 6 Drops	7 - 11 drops	
Vats - Long	4 - 6 Drops	5 - 15 Drops	4 - 6 Drops	7 - 11 drops	
Big Line / Curd Line	4 - 6 Drops	5 - 15 Drops	4 - 6 Drops	7 - 11 drops	
Seperator	4 - 6 Drops	5 - 15 Drops	4 - 6 Drops	7 - 11 drops	
Concentrations	# of drops x 0.1 = %	# of drops x 10 = ppm	# of drops x 0.1 = %	# of drops x 13 = ppm	

Date: 10/26/2013 Supervisor Review:

Caustic Test Result	Chlorine Test Result	Nitric Acid 30% Test Result	Sanitizer Test Result	Initials
5	14	6	10	AR

Supervisor Review:

Caustic Test Result	Chlorine Test Result	Nitric Acid 30% Test Result	Sanitizer Test Result	Initials
4	12	5	9	DP

Seperator

Comments:

Date: 10/28/2013 Supervisor Review:

Equipment Washed Check One		Caustic Test Result	Chlorine Test Result	Nitric Acid 30% Test Result	Sanitizer Test Result	Initials
	Vats - Short	6	15	6	8	AR
X	Vats - Long					
	Big Line / Curd Line					
	Seperator					

Date: 10/29/2013 Supervisor Review:

Equipment Washed Check One		Caustic Test Result	Chlorine Test Result	Nitric Acid 30% Test Result	Sanitizer Test Result	Initials
	Vats - Short	5	13	6	9	AR/BR
	Vats - Long					
X	Big Line / Curd Line					
	Seperator					

Comments:

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Pre-Operational Inspection

DAILY INSPECTION **VAT PRE-OP**

Document all findings.

Re-wash any Vat found to be not satisfactory.

DATE:

TIME: 6:10AM

OO Vat #	*Checked*	*Operator*	*Comments*
1	X	JAM	
2	X	JAM	
3	X	JAM	
4	X	JAM	
Dipper	X	JAM	
Curd Hose	X	JAM	
1 Discharge valve	X	JAM	
2 Discharge valve	X	JAM	
3 Discharge valve	X	JAM	
4 Discharge valve	X	JAM	
Visually inspect inside of OO Vats for cheese and cleanliness (LOWER AGITATOR SHAFTS CHECKED)		JAM	
		JAM	

Visually inspect over equipment vessels for possible extraneous material

	Broken	*Not Broken*	*Operator*
Light fixtures		X	JAM
	Pieces Missing	*Pieces Not Missing*	*Operator*
overhead structures (pipes, beams, cords, etc...)		X	JAM

	Checked	Operator	Date
Is the equipment Properly Assembled	X	JAM	31-Oct

Document shall be forwarded to Supervisor daily.

Supervisor Verificati

Be specific on observations. Does "checked" mean clean?

Date: 4-4-13 Time (Military): 1500 Trailer No. 6 Dock #: 6

.. Wheels on the trailer chocked KW (Initials) - Wheels on trailer must be chocked and verified by SFI partner

2. Dock Lock locked KW (Initials) - Dock lock must be locked. (If Dock not equipped with Lock write N/A).

3. Verified Drivers License: Yes / No [redacted] Driver Dock Boots in place: Yes / No

4. Trailer is in sound condition with no damage to side walls: Yes / No
If damage is present, ensure product is not or will not be impacted. Report damage to driver to be repaired.

NOTE: IF ITEMS 1 & 2 ARE NOT IN PLACE - DO NOT UNLOAD/LOAD THE TRAILER

Inspect the trailer for the following items and place an "X" in the appropriate column.

	ACCEPT	REJECT	Corrective Action
Floor is clean and in sound condition	X		
Landing gear is in proper position if the tractor has been un-hooked from the trailer	X		
No signs of insects, rodents or bird infestation	X		
Free of non-food grade chemicals	X		
No raw meat, poultry or fish; or raw unpacked produce	X		
Product is free from signs of tampering, damage or suspicious appearance	X		
No off odors	X		
Reefer Setting Within Spec N/A °F (33-38 degrees)	initial	Initial	
	KW		Dry Box
Trailer in good sanitary condition	X		
Product in good sanitary condition	X		

Trailer Security Verification - Trailer seal number must match BOL.
If it does not match, fill out the Improperly Sealed Trailer Incident Report and contact QA.
Number

Outbound Trailer: _____ Document Seal # on Shipping paperwork

Inbound Trailer: 978086

**Matches seal number on BOL or SO: Yes / No Initial: KW

Rejection on any of the above items will require QA approval before trailer may be loaded or unloaded.

DISPOSITION (CIRCLE ONE) ACCEPTED / REJECTED

Loader/Unloader (Signature) _____ Verified as Completed by (Signature) _____

[redacted] or Designee required for non-conformances (Signature) _____

: This form must be filled out completely by the Plant partner who "Receives" a load or "Loads" a trailer. Failure

Shipping & Receiving

Actual Data Values When Applicable

Reefer Setting Within Spec N/A °F (33-38 degrees)	Initial	Initial	
	KW		Dry

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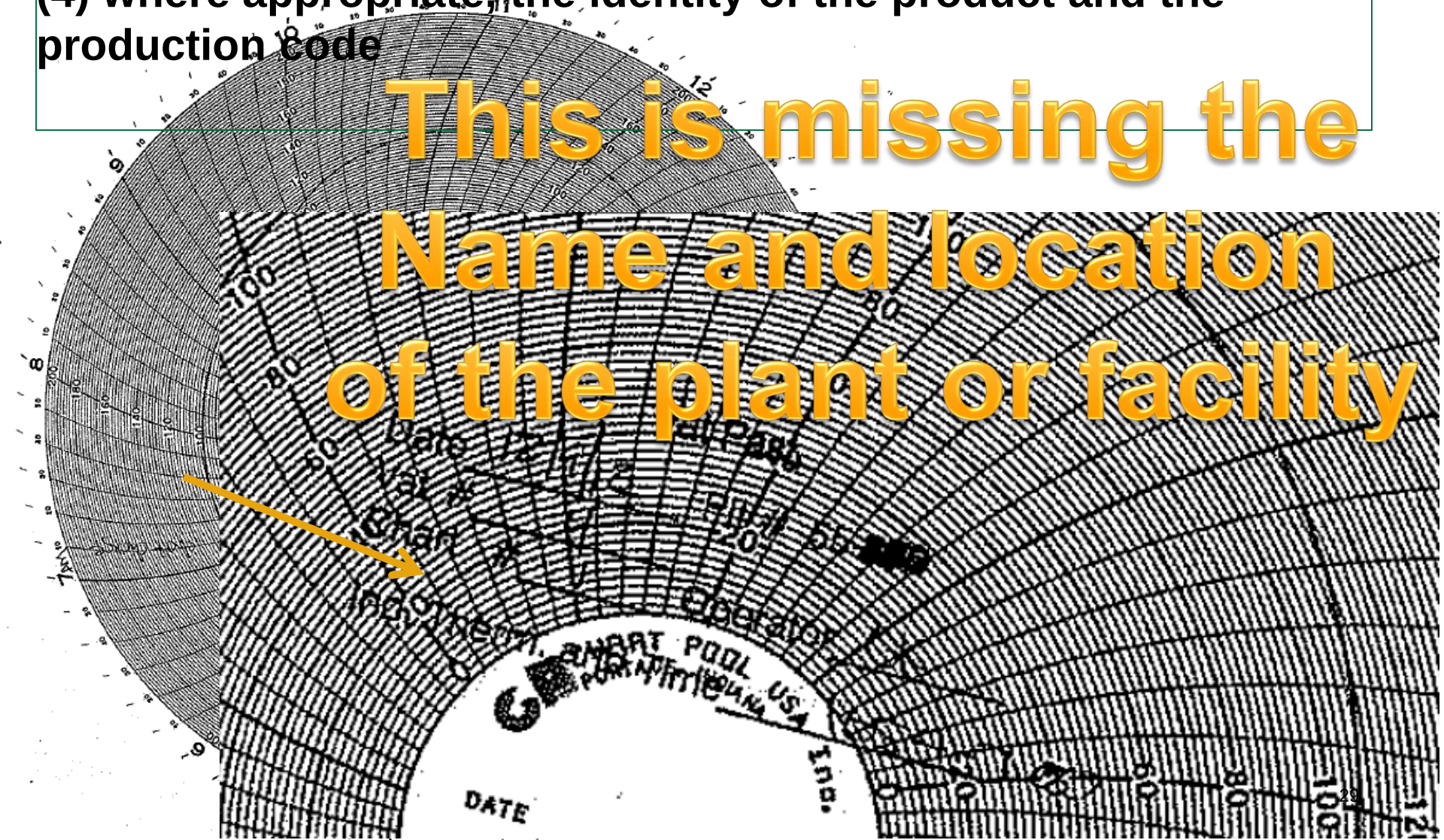
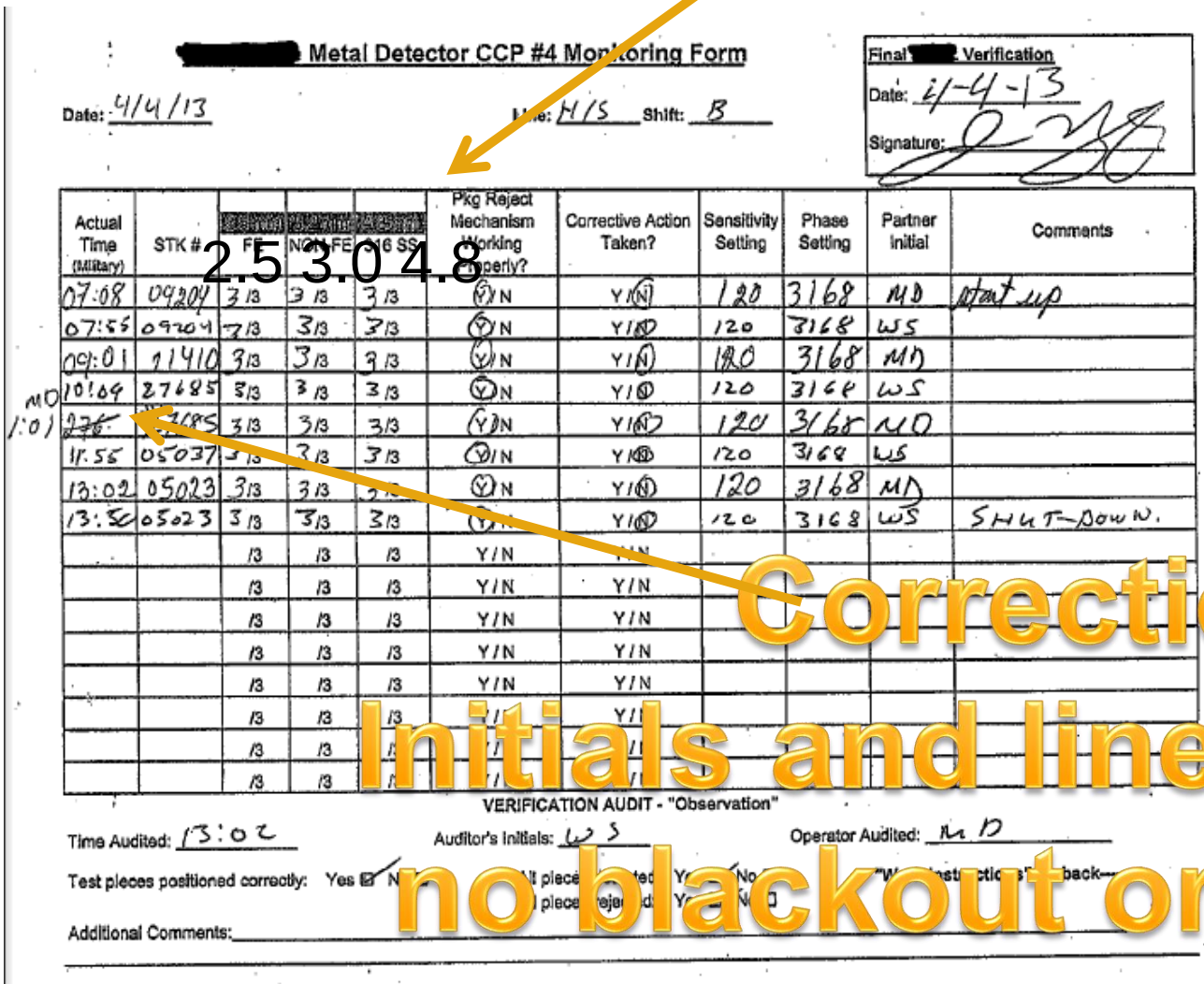
Continuous Data And Identification Components

Identification: The name and location of the plant or facility; (2) the date and time of the activity documented; (3) the signature or initials of the person performing the activity; and (4) where appropriate, the identity of the product and the production code



Critical limits if applicable



[redacted] Metal Detector CCP #4 Monitoring Form

Date: 4/4/13 Line: M/S Shift: B

Final [redacted] Verification
Date: 4-4-13
Signature:

2.5 3.0 4.8

Actual Time (Military)	STK #	[redacted] FE	[redacted] NON-FE	[redacted] 316 SS	Pkg Reject Mechanism Working Properly?	Corrective Action Taken?	Sensitivity Setting	Phase Setting	Partner Initial	Comments
07:08	09204	3/3	3/3	3/3	Y N	Y N	120	3168	MD	start up
07:55	09204	3/3	3/3	3/3	Y N	Y N	120	3168	WS	
09:01	11410	3/3	3/3	3/3	Y N	Y N	120	3168	MD	
10:04	27685	3/3	3/3	3/3	Y N	Y N	120	3168	WS	
MD 1:01	27685	3/3	3/3	3/3	Y N	Y N	120	3168	MD	
11:55	05037	3/3	3/3	3/3	Y N	Y N	120	3168	WS	
13:02	05023	3/3	3/3	3/3	Y N	Y N	120	3168	MD	
13:50	05023	3/3	3/3	3/3	Y N	Y N	120	3168	WS	SHUT-DOWN.
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				
		/3	/3	/3	Y/N	Y/N				

VERIFICATION AUDIT - "Observation"

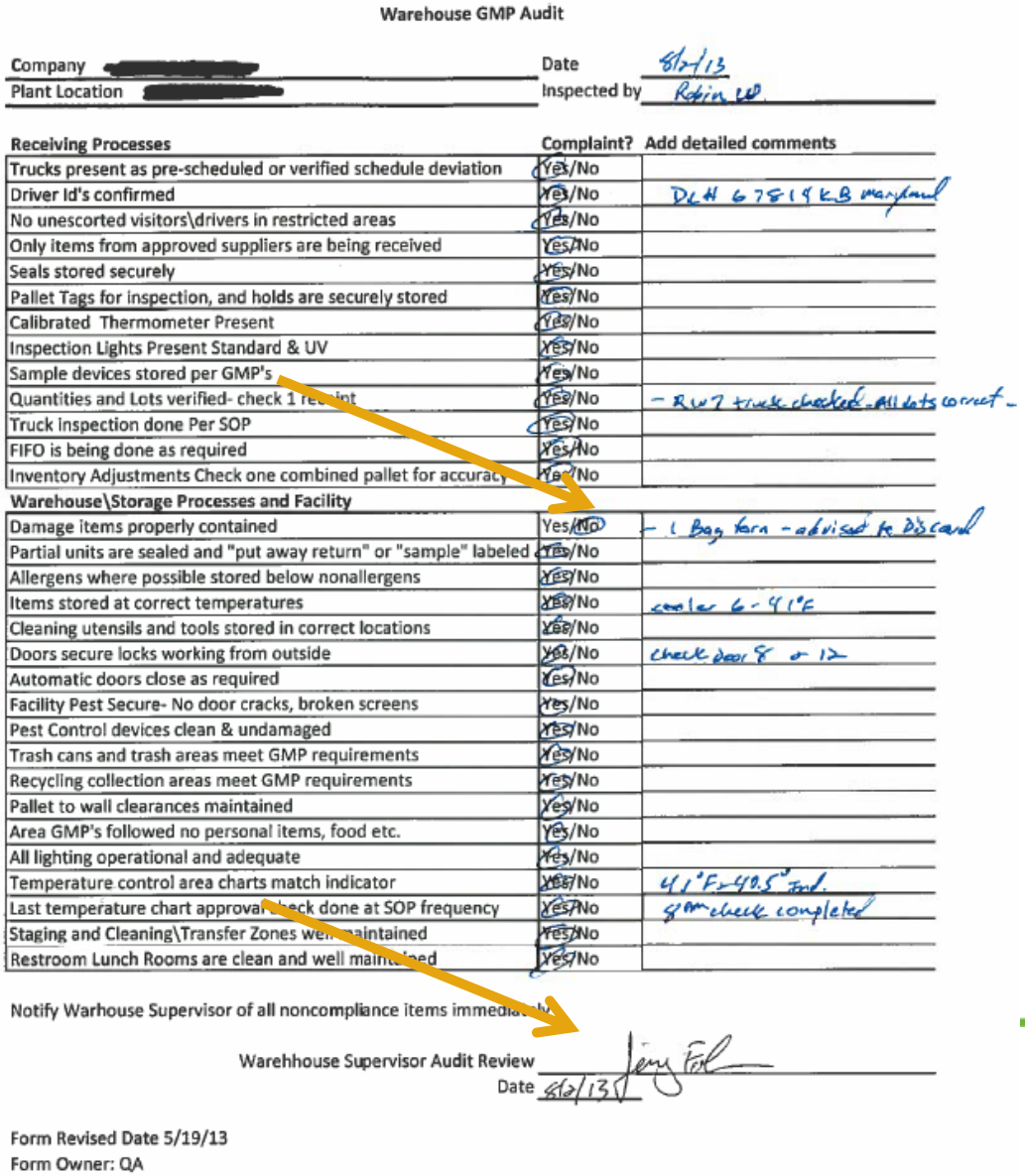
Time Audited: 13:02 Auditor's Initials: WS Operator Audited: MD

Test pieces positioned correctly: Yes ☑ N

Additional Comments:

Corrections
Initials and lined through
no blackout or whiteout

Document follow up



Warehouse GMP Audit

Company [redacted] Date 8/7/13

Plant Location [redacted] Inspected by Robin LD

Receiving Processes	Complaint?	Add detailed comments
Trucks present as pre-scheduled or verified schedule deviation	Yes/No	
Driver Id's confirmed	Yes/No	DLH 67514 KB maryland
No unescorted visitors\drivers in restricted areas	Yes/No	
Only items from approved suppliers are being received	Yes/No	
Seals stored securely	Yes/No	
Pallet Tags for inspection, and holds are securely stored	Yes/No	
Calibrated Thermometer Present	Yes/No	
Inspection Lights Present Standard & UV	Yes/No	
Sample devices stored per GMP's	Yes/No	
Quantities and Lots verified- check 1 receipt	Yes/No	- RW7 truck checked - All dats correct -
Truck Inspection done Per SOP	Yes/No	
FIFO is being done as required	Yes/No	
Inventory Adjustments Check one combined pallet for accuracy	Yes/No	
Warehouse\Storage Processes and Facility		
Damage items properly contained	Yes/No	- 1 Bag torn - advised to Discard
Partial units are sealed and "put away return" or "sample" labeled	Yes/No	
Allergens where possible stored below nonallergens	Yes/No	
Items stored at correct temperatures	Yes/No	cooler 6 - 41°F
Cleaning utensils and tools stored in correct locations	Yes/No	
Doors secure locks working from outside	Yes/No	check door 8 & 12
Automatic doors close as required	Yes/No	
Facility Pest Secure- No door cracks, broken screens	Yes/No	
Pest Control devices clean & undamaged	Yes/No	
Trash cans and trash areas meet GMP requirements	Yes/No	
Recycling collection areas meet GMP requirements	Yes/No	
Pallet to wall clearances maintained	Yes/No	
Area GMP's followed no personal items, food etc.	Yes/No	
All lighting operational and adequate	Yes/No	
Temperature control area charts match indicator	Yes/No	41°F - 40.5° Ind.
Last temperature chart approval check done at SOP frequency	Yes/No	8am check completed
Staging and Cleaning\Transfer Zones well maintained	Yes/No	
Restroom Lunch Rooms are clean and well maintained	Yes/No	

Notify Warhouse Supervisor of all noncompliance items immediately

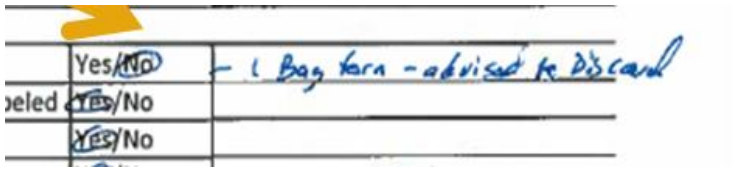
Warehhouse Supervisor Audit Review Jerry Fox

Date 8/12/13

Form Revised Date 5/19/13

Form Owner: QA

- Create a Paper Trail
- Documented link between issue and correction
- Sign document to show who took corrective action



Corrective & Preventive Action (CAPA) Form

Reference #	Date	Dept	Line			Assigned To
1900	2/5/13	Shred	B8			[redacted]

Initiated By: [redacted] CCP: x CQP:

Description (Event details including time)

Operator was performing a metal detector check at 08:51, the non-ferrous wand only rejected 1/3 times. The metal detector detected but failed to blow the bags off of the line. Line was stopped and maintenance was called.

Root Cause

Air nozzle slid down (is adjustable) and was blowing at the side of the belt instead of right above it.

Product: Was all product run after last successful check placed on Hold? Yes x No ____

Summary Of Finished Product Held (Including All WIP)

Bulk Class Code/ Stock #	Make Date/Julian Date	Qty Held	Disposition
20788	2/5/13 036	90 cases	To be run through a functioning metal detector

Additional Findings – Once disposition is complete, etc.

The packages were re-run through a functioning metal detector and released.

Corrective Action

All product since the last good check was placed on hold, STK 207[redacted] units 1435115 and 1435116.
Nozzle was adjusted, operator performed another metal detector check at 09:05 and all packages were rejected.

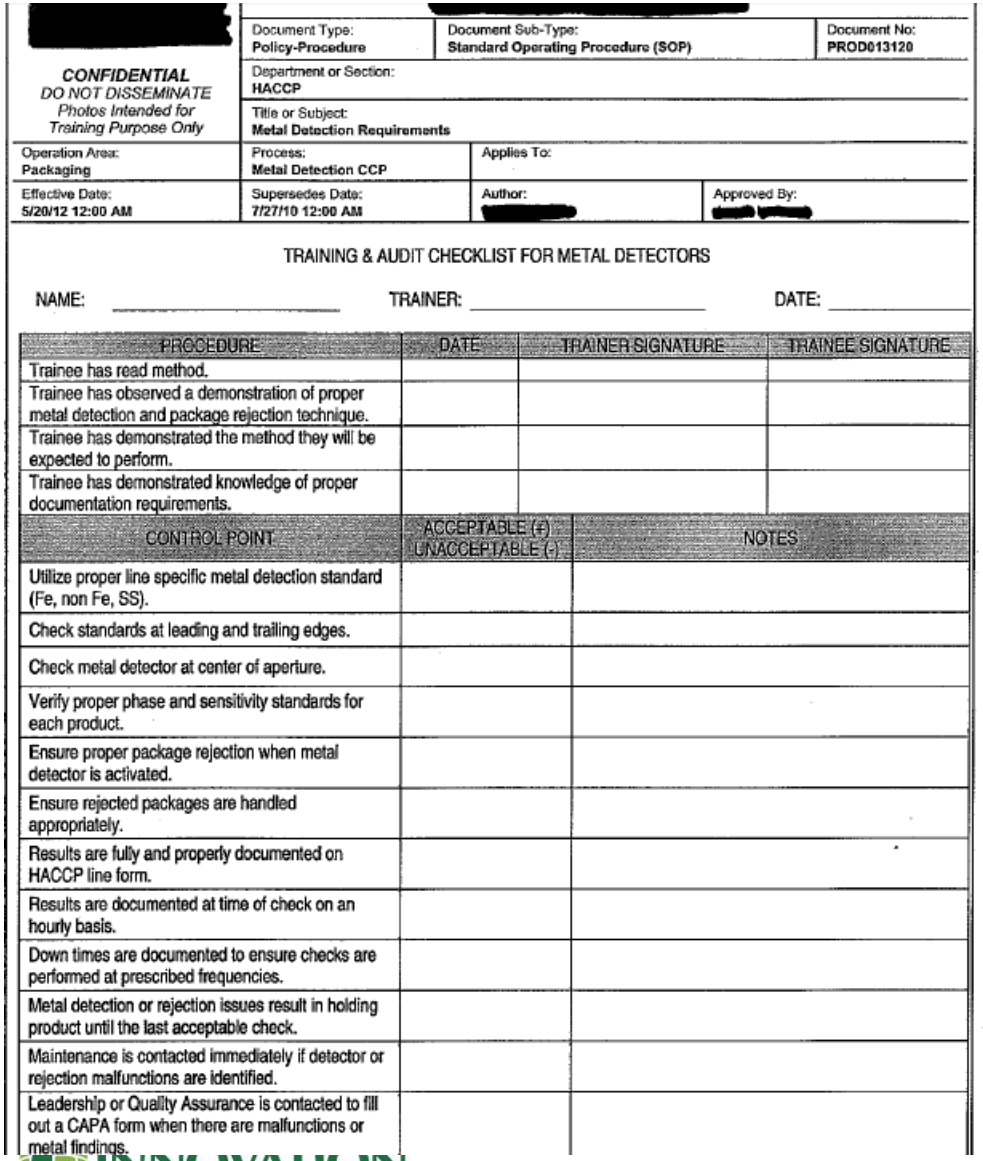
Preventative Action (what is being done long term)

Nozzles for lines 7 and 8 were welded in place by maintenance so they cannot slip out of place.

Due Date: (96 hrs after occurrence) 2/11/2013 Completion Date: 2/10/13 [redacted] Signature: [redacted]

Verified By: [redacted] Closed Date: 2/13/13

Clarity is important in describing what is being documented



[redacted]

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Photos Intended for Training Purpose Only

Document Type:	Document Sub-Type:	Document No:
Policy-Procedure	Standard Operating Procedure (SOP)	PROD013120

Department or Section: HACCP

Title or Subject: Metal Detection Requirements

Operation Area:	Process:	Applies To:	
Packaging	Metal Detection CCP		
Effective Date:	Supersedes Date:	Author:	Approved By:
5/20/12 12:00 AM	7/27/10 12:00 AM	[redacted]	[redacted]

TRAINING & AUDIT CHECKLIST FOR METAL DETECTORS

NAME: _____ TRAINER: _____ DATE: _____

PROCEDURE	DATE	TRAINER SIGNATURE	TRAINEE SIGNATURE
Trainee has read method.			
Trainee has observed a demonstration of proper metal detection and package rejection technique.			
Trainee has demonstrated the method they will be expected to perform.			
Trainee has demonstrated knowledge of proper documentation requirements.			

CONTROL POINT	ACCEPTABLE (+) UNACCEPTABLE (-)	NOTES
Utilize proper line specific metal detection standard (Fe, non Fe, SS).		
Check standards at leading and trailing edges.		
Check metal detector at center of aperture.		
Verify proper phase and sensitivity standards for each product.		
Ensure proper package rejection when metal detector is activated.		
Ensure rejected packages are handled appropriately.		
Results are fully and properly documented on HACCP line form.		
Results are documented at time of check on an hourly basis.		
Down times are documented to ensure checks are performed at prescribed frequencies.		
Metal detection or rejection issues result in holding product until the last acceptable check.		
Maintenance is contacted immediately if detector or rejection malfunctions are identified.		
Leadership or Quality Assurance is contacted to fill out a CAPA form when there are malfunctions or metal findings.		

Document training and be specific

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HEALTHY PEOPLE • HEALTHY PRODUCTS • HEALTHY PLANET

Narrative Record Examples

- "Work area was a mess, what a disaster"

- "Observed that the Line 2 work area at 2 pm needs to be more organized"

- Accurate, Defined, Good Word Choice
- When stating facts choose words that effectively communicate the item without being inflammatory.
- Example: Metal found 1.0 mm X2.1 MM X 1mm vs. ~~Sharp Metal Sliver~~

Example Records - Summary

- Identification
  - The name and location of the plant or facility
  - The date and time of the activity documented
  - The signature or initials of the person performing the activity
  - Where appropriate, the identity of the product and the production code, if any
- Contain the actual values and observations obtained during monitoring and be as detailed as necessary to provide a history of work performed
- Contain critical limits where necessary
- Accurate, indelible, and legible
- Created concurrently with performance of the activity documented
- Originals or if electronic be 21 CFR part 11 compliant
- Key Food Safety Documents signed/reviewed in designated time periods by properly trained personnel / Qualified Individual

Conclusion

Overall Conclusions

- Creating and implementing a Food Safety Plan ensures we are meeting consumer safety needs AND complying with food safety laws.
- FSMA mandates making and maintaining Records that support Food Safety Plans
- Records “tell the story” of what happened at some point in the past, they must be clear and accurate.
  - If it is not documented, it did not happen!
  - If it is documented, it happened exactly that way
- Good Records speak for themselves. They remove the need for guessing or assuming what happened.

Consumer Food Safety is the goal!

- Documenting is a way to ensure that the right things are being done the right way in a consistent fashion. Records are a means to an end, not the end goal.
- Records are a good way to demonstrate the FSP was followed and safe product was produced.
- Good Recordkeeping provides an objective way to review if changes are needed. This fuels continuous safety improvements.
- This is consistent with both regulatory and consumer interests.

Q & A

This Webinar was prepared by:

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Presentation materials available at: **www.usdairy.com/foodsafety**