



Reichel Foods, Inc.

Employee Warning Notice

SQ0014FO

R: 2

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Employee Information

Date: 8/4/2016
Employee Name: Laura Chaw
Job Title: QA Tech
Manager/Supervisor: Luz Pizano

Type of Warning

Verbal Warning
Written Warning
Final Warning

Type of Offense

Tardiness/Leaving Early
Absenteeism
Violation of Company Policies
Substandard Work
Violation of Safety Rules
Rudeness to Customers/Coworkers
Other

Details

Description of Incident (Describe incident and list the date, time, and any witnesses present)

On 08/02/16 and 08/03/16 Laura was seen conducting her metal detector check on the Orics line incorrectly and deviating from the written procedure stated on the Metal detection verification work instruction (QA0206WI). Laura was appropriately trained on how to conduct the Metal detector check on 10/13/14, she had another training specific to the metal detector check procedure on 5/28/15. ~~conducting this specific check was mentioned during several QA meetings throughout the end of 2015 going into 2016.~~ She also signed a training record on 12/2/15 for the Metal detector retraining. Laura documented a metal detector check at 12:50pm on 8/3/16 but didnt conduct a check at that time. Recently she has also had Record Control Training on 05/19/16.

Plan for Improvement:

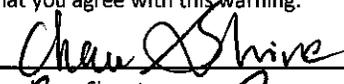
Laura will be re-trained on conducting a metal detector check and will perform a check with QA Supervisor to verify that she conducts the check correctly.

Consequences of Further Infractions:

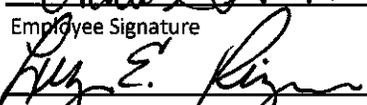
Any further metal detector checks done incorrectly will result in a final warning, including but not limited to disciplinary action and/or termination of employment.

Acknowledgement of Receipt of Warning

By signing this form, you confirm that you understand the information in this warning. You also confirm that you and your manager/supervisor have discussed the warning and a plan for improvement. Signing this form does not necessarily indicate that you agree with this warning.


Employee Signature

08 04 16
Date


Manager/Supervisor

08/04/16
Date

Witness Signature (if employee understands warning but refuses to sign)

Date

Request

CAPA Number: 615

Action Required: CA

Reason: External Audit

Reference Standard or Policy: Other

Nature of Problem (in detail): SQF Audit: During observation of the metal detector testing in MV2 and MV1 on 5/27 the test pieces were detected, but not consistently rejected. In some cases the air jet rejected the wrong package and in some cases the air jet was not strong enough to reject the detected product.

Evidence: Observation of MV1, MV2 and Orics 6 metal detector checks on 5/27/15.

Investigation and Action Plan

Action Plan Karin Grzanek

Completed by:

Root Cause:

- 1.The QA Technicians were not allowing enough time for the reject mechanism to work properly before hitting the reset button on the metal detector (to prevent product trays from backing up and dropping off the line). In addition, they were grabbing the wand off the package prior to rejection so they didn't always notice that the wrong tray was rejected.
- 2.Some QA Technicians were placing the wand parallel to the tray so that the metal seed would either be in front of or behind the actual tray location. This caused the air blow reject mechanism to target the metal seed and miss the tray in some cases.
- 3.Password protection for the metal detector settings was not in use. Unauthorized employees could change the program or the sensitivity levels.
- 4.The air nozzles move easily when bumped, so frequent adjustment was needed to insure the blow off was working correctly.
- 5.The air nozzle blow off pressure was adjustable on two of the lines, so an employee could turn the air pressure down without authorization to do so. This would affect the ability of the equipment to reject trays properly.

Action Plan:

- 1.Retaining was completed with QA to insure they conduct the metal detector verification properly, to include how and where to place the wand, insuring that the wand/tray is rejected into the bin and verifying that affected trays are rejected. See Metal Detection Verification Work Instruction QA0206WI.
- 2.Password protection is in use on each metal detector allowing only maintenance access. QA will verify that the correct program is in use during each metal detector check with documentation on the Metal Detector Checks Form, QA0065FO.
- 3.The air blow off reject mechanism was replaced with a reject arm mechanism that diverts all product trays on the conveyor into the reject bin, while the belt continues to run.
- 4.A visual verification of the QA Metal Detector Verification process will be conducted by the QA Supervisor on a weekly basis to insure employees are following proper procedure.

Implementation 6/8/2015

Dates:

Follow Up

Request

CAPA Number: 615

Objective evidence noted (for EACH action plan step): 1. Retraining was conducted on 6/5/15. 2. Spoke with various maintenance, QA and production personnel. The program in the MD is password protected. Maintenance is the only department with the password. QA is verifying the program for each line and recording it on QA0065FO R15. 3. Not all trays were going into the bin on MV2 during checks. The tray after the one with the wand and all following trays would get stuck on 6/29/15. On 6/30, the Rotary MD had trays following the wand tray stick on the belt and not fall into the bin during multiple checks. 4. Weekly verification by the QA Supervisor were deficient per the procedure/form. During the weeks of 6/15 and 6/22, only 2 of the lines on 1st shift were documented as verified and no 2nd shift techs were verified.

Action Plan Completed on Time? Yes

If not, why?: Not all action items

Corrective Action Effective? No

Effectivity Notes: All employees from all departments interviewed displayed strong knowledge of the processes. Copy of observations attached. Went through all metal detector check forms between 6/8 and 6/30 and there was only 1 deficiency noted on the form. In all required checks reviewed, the tray with the wand fell in the bins on all lines, except on the rotary on 6/30. The arm rejected the tray, but when the arm returned to position, the tray went down the line. Notified maintenance and the metal detector height was adjusted. All further checks were acceptable. The air pressure was strong enough in all cases to reject the product. There have been no customer complaints involving metal during this period.

Completion Date: 7/6/2015

Follow Up Completed By: Jamie Sorensen

CAPA Status: Reissued

Close Out Date:

New CAPA Number:

Attachments:

To view attachments, return to menu and enter the CAPA number desired into the CAPA Follow Up Form.

Reichel
QA Tech Training Checklist

Date	Trainer Initial	Super-visor Initial	
11/04/14	JT	YP	Solution Checks (Titration, Dip tests) – Apples, Carrots (QA0193WI)
10/20/14	CMR	YP	Apple Slice Quality Check (QA0012FO)
10/31/14	CMR	YP	Residual Gas Analysis Check (Residual MAP Test Instructions QA0198WI)
10/13/14	CMR	YP	Metal Detector Check (QA0065FO)
10/31/14	CMR	YP	Net Weight Checks (USDA & FDA)-Finished Product Net Weight Instructions QA0238WI
10/31/14	CMR	YP	Sampling, Analysis & Inspection (QA0254PR)
11/04/14	JT	YP	Reichel Pre-op and Operational Checks (QA0520WI and Pre-Op forms)
11.04.14	SP	YP	FDA HACCP Visual Verification & Pre-ship Review (FDA HACCP Plans)
10/31/14	CMR	YP	Cartoner Room Checks (Product ID & Traceability QA0225PR)
11/04/14	JT	YP	Case Label Barcode Check (Barcode Verification Work Instruction-QA033WI)
10/31/14	CMR	YP	QA Verification Checks (2 hour)
11.04.14	SP	YP	Daily Product Evaluations (Taste Test) (Organoleptic Evaluation of Finished Product QA0200WI)
11/05/14	JT	YP	Thermometer Calibrations (Thermometer Calibration Verification QA0153WI)
11/04/14	JT	YP	Peanut Butter Pre-Op and Swabs (See Pre-op forms and QA0520WI)
11/04/14	JT	YP	Shipping & Receiving Procedure & Shipping/Receiving Inspection Form (WH0001PR, WH0004FO)
11/05/14	JT	YP	QA HOLD Process (Nonconforming Product & Equipment Procedure QA0218PR)
11/04/14	JT/CMR	YP	Micro Samples (pre-op swabs, <u>first off the line</u> , <u>finished product</u> , air plates as applicable)
11/05/14	JT	YP	Rework QA Verification Form (QA0069FO) & Product Re-Work Instruction QA0506WI
10/31/14	CMR	YP	Collecting Retain Samples (Retention Sample Work Instruction QA0201WI)
11/05/14	JT	YP	Allergen Control Program QA0219PR & Allergen Control Cleaning Chart QA0389WI
11/05/14	JT	YP	HACCP Programs (See HACCP Binder FDA)
11/05/14	JT	YP	SSOP Program (Sanitation SOP QA0089PR & Reichel Foods Sanitation SOP QA0268FO)
10/31/14	CMR	YP	Employee GMP's (Good Manufacturing Practices-QA0183WI)
11/05/14	JT	YP	Customer Complaint Procedure (QA0187PR)
11/05/14	JT	YP	Sanitary Handling of Backed Up Drains Procedure (QA0220WI)
10/31/14	CMR	YP	Finished Product Specifications (QA0483WI)
10/20/14	CMR	YP	License Plate/Kitting (QA0488WI)

I have been trained and understand my responsibility for each of the QA tasks listed above.

Employee Signature: Chaw Shine

Date: 11/06/14

Trainer Signature: Christine Richardt

Date: 11/4/14

Hendria Gunt

11/6/2014 RC

Production Schedule: No Weekend. T&H next week is Tuesday

Sale Samples. Reiterate the importance of samples because a few cases weren't collected last night and these were going out today.

SQF Audit. Major Nonconformance

#1 SQF Standard 11.7.6.2 - Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

Major Nonconformance- During observation of the metal detector testing in MV2 and MV1 on 5/27 the test pieces were detected, but not consistently rejected. In some cases the air jet rejected the wrong package and in some cases the air jet was not strong enough to reject the detected product.

Metal detector blow off doesn't blow off the tray with the wand on it. MV2 metal detector was blowing the next tray off. MV1 metal detector air blow wasn't strong enough. O6 also wasn't working properly. QA techs weren't recognizing this wasn't working properly because they were resetting the belt so quickly in order to avoid product being backed up.

MD training- new procedure, form update.

- Wand must be inserted into tray with product in it.
- Product and wand must be allowed to go into bin so we can insure it is working how we intend it to.
- The 'blow off' has been replaced with a 'reject arm'.
- The belt will continue running instead of stopping.

Other Items Noted during audit to be aware of:

- Employees were dragging white tubs across tubs of apples. PAA hose was sitting in water.
- An employee pulled a tub of PAA that had already been used for soaking slices and when it was going to be discarded, the employee topped off other tubs with the used solution (onto apples already soaking) and then carried the remainder of the tub to the discard barrel.
- Op checkers need to wash their hands before touching apples. They should not re-use plastic sampling cups or "dunk" them into apple tubs. Slicing employees should use their stainless steel scoops to get them samples so they don't have to stick hands in water.
- Employees seemed to be filling the slotted trays too full to achieve proper coverage of PAA and calcium ascorbate.
- Whole apples were overfilled so even with the weights on top; we saw two soak tubs with some whole apples over the solution level.
- Employee was scooping stickered apples out of 1st PAA soak using a slotted tray and dumping back into the corrugated box; this will cause damage to the fruit.
- Batching Area - Scale needs to be kept on the table (flat sturdy surface); should not be stored on the calcium chloride bucket.
- Employees were putting the sanitized bags of celery directly into a slotted tray and then opening the bags and dumping the celery into the same slotted tray and in some cases right on top of the unopened bags. They're making those bags Zone 1 surfaces and that isn't the intent in sanitizing the outside of the bag. The celery shouldn't contact the outside of the bag. (This was corrected before the 2nd shift walk through)
- MV2 – an open tube of food grade grease was left sitting in the 3 compartment sink; 2nd shift sanitation found it. I threw it away.
- Front hall, main plant – Calcium Ascorbate boxes were very dirty (pic)
- MV1 - blue wand failed 2 out of 3 times during metal detector check.

