

Most Common SQF Non Conformances

Jeanette Litschewski
SQFI Technical Affairs Specialist

Agenda

Intro. SQF and the
audit in Review



Non Conformances

- Records
- Food Safety System
- Environmental Monitoring
- Internal Audits
- Food Fraud
- Food Defense
- Construction of Premises/Equipment
- Pest Prevention
- Cleaning/Sanitation
- Personnel Processing Practices
- Foreign Object Detection



Five Takeaways Other

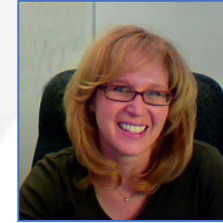
- SQF Conference
- Q&A

SQF Technical Team



LeAnn Chuboff, VP, Technical Affairs

Kristie A. Grzywinski, Sr. Technical Manager



Jeanette Litschewski, Technical Specialist

Bill McBride, Asia Pacific Representative



Frank Schreurs, Canadian Representative



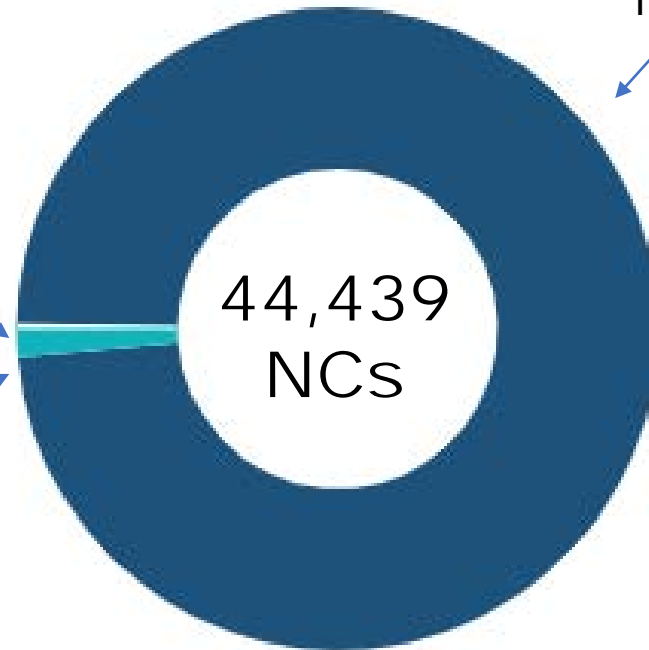
A Review of SQF in 2018

January-December 2018

7710
Closed Audits

0.06%
critical

1.6%
major



44,439
NCs

98.4%
minor

5.76
NCs per audit

My Parent's First Date

Minor: An omission or deficiency in the SQF System that produces unsatisfactory conditions that if not address may lead to a risk to food safety but not likely to cause a system element breakdown. 1pt

Major: An omission or deficiency in the SQF System producing unsatisfactory conditions that carry a food safety risk and are likely to result in a system element breakdown. 10pts

Critical: A breakdown of controls at a critical control point, a pre-requisite program, or other process step and judged likely to cause a significant public health risk and/or where product is contaminated. 50pts.



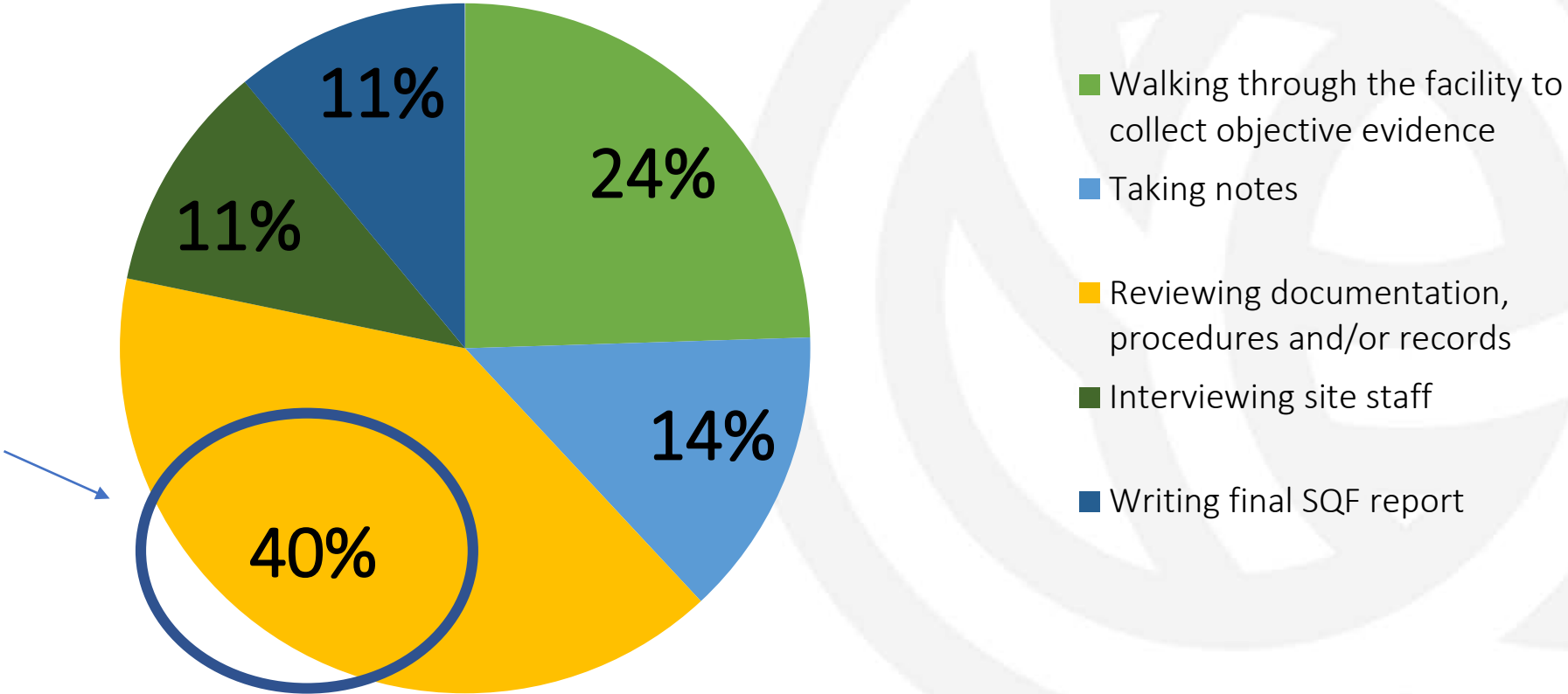
2.2.3 Records

2.2.3.2 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

2.2.3 Records: What NCs are we seeing?

- “Review of the records found them **incomplete, missing cleaning activity** entries for at least the last two months.”
- “Review of selected production batch record forms including QC worksheets and blending records noted several documents **missing required verification signatures, activity dates and write-overs.**”
- “Not all records were completely **legible**. Some records reviewed had some cross outs, write overs or corrections without properly documenting such as shipment records, internal audits and production records.”

Breakdown of Audit Activities



2.4 Food Safety System

2.4.3.13 (Food Safety Plan) The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits. Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

1. Identify CCPs and their respective limits
2. Identify personnel assigned to conduct testing
3. Identify tests needed and test frequency

2.4.3.2 (Food Safety Plan) The food safety plan shall be effectively implemented and maintained and outline the means by which the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

1. Create your HACCP plan(s)-> identify CP and CCPs
2. Implement your HACCP plan

2.4.3.13 Food Safety System: What NCs are we seeing?

Upon reviewing of records from June 12 and June 13, 2017 monitoring checks were documented with **temperatures from 40.3 to 41.0° F which is above the critical limit** as established by the facility. **No corrective action was documented** for any of these deviations.

Facility procedures define that any failed detection or rejection of a test wand on the CCP Metal Detector requires a product hold and proper communication. On Line #3, an interview was conducted with the employee performing monitoring activities of the CCP Metal Detector, however **the employee clearly was not aware of proper procedures and communicated a practice that would lead to food safety concerns.**

Several monitoring records showed that the pH results exceeded the Critical Limit for pH 4.2 ± 0.3 as per HACCP Audit Table. **No corrective action taken or recorded on the monitoring records.**

Procedure to monitor CCPs to ensure they remain within established limits is **not fully implemented**- monitoring records to support CCP1 critical limits of approved C of A for specified ingredients prior to use were not available at time of audit.

2.4.3.2 Food Safety System: What NCs are we seeing?

“During review of the Preventative Controls program, it was observed that the facility has **not included all products in the program.**”

“The metal detector was a designated CCP for this site. When the unit was tested during the floor inspection by the employee designated to monitor the device, two 1.5mm FE wands and one 1.5mm NF wand were used for the test. The HACCP plan called for FE, NF and SS wands be used for the test (all 1.5mm). When questioned, the employee went to her work station and returned with a 2mm SS test wand and again tested the unit. When again questioned, the employee left and returned with the correct wands and successfully tested the unit (it functioned normally).

When asked what should be done if the metal detector failed to properly detect targets, the employee stated that the metal detector should be repaired by maintenance. When asked what about the potentially affected product she was unable to articulate holding back to the last good check (which is a plan requirement) until she was asked that question several times.”

2.4.8 Environmental Monitoring

2.4.8.1 (Environmental Monitoring) A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

1. Create a team to determine risks to the site-potential pathogens?
2. Determine appropriate methods to mitigate identified risks
3. Create a schedule

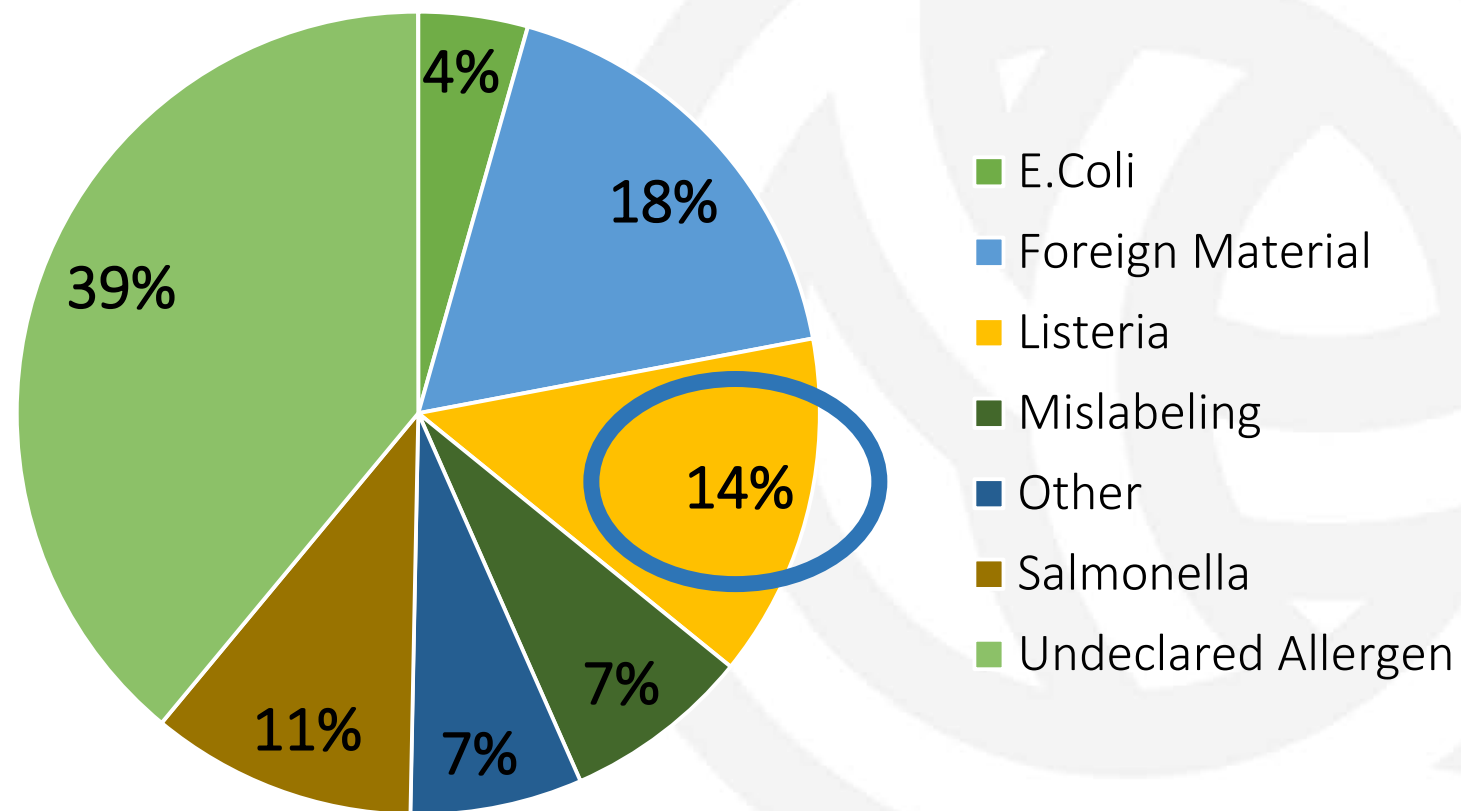
2.4.8 Environmental Monitoring: What NCs are we seeing?

“The Environmental Monitoring SOP calls for swabbing for E. coli, and Salmonella, along with Listeria monocytogenes. Swabbing has not been done for E. Coli or Salmonella.”

“There is no evidence that a risk based environmental program has been developed.”

“There is no environmental monitoring program in place. The plant is doing swabs in surfaces in contact with food only. No risk analysis, no tests on environment and nothing written for environmental monitoring was available.”

Reasons for Recalls



2.5.5 Internal Audits

BRACE YOURSELVES

**INTERNAL AUDIT IS
COMING**



2.5.5.1 (Internal Audits and Inspections) The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted at least annually. The methods applied shall ensure:

- i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool;
- ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken;
- iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions.

2.5.5 Internal Audits: What NCs are we seeing?

“Plant has **not conducted an internal audit** of their program in the last 12 months.”

“Internal audit program was **not effective to identify non-conformances** raised during this audit, opportunities for improvement and to identify the effectiveness of the SQF system.”

How to Be Compliant?



2.7 Food Fraud and Food Defense

2.7.2.1 (Food Fraud) The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

2.7.1.3 (Food Defense) The food defense plan shall be reviewed and challenged at least annually.

Food Fraud: 756 NCs
Food Defense: 965 NCs

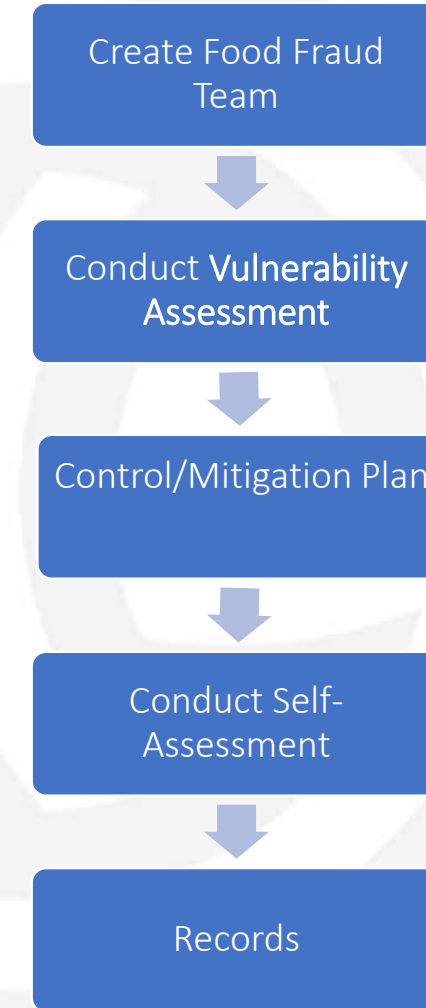
Food Fraud: Here's What You Need to Do



“A Food Fraud vulnerability assessment **had not been completed** by the site at the time of audit.”

“The methods, responsibility and criteria for identifying the site's vulnerability to food fraud **has not been documented, implemented and maintained.**”

How to Be Compliant?



Resources

Michigan State University

- Free online food fraud courses

Pwc and SSAFE

- Free online food fraud vulnerability assessment

SQF Tip Sheets

Food Defense: Here's What You Need to Do



Resources

SQF Tip Sheet

FDA Food Defense Builder

USDA Functional Food Defense Plans

“Last Food Defense Plan challenge was **not documented.**”

“Review of the food defense program found that the food defense plan has **not been reviewed and challenged annually.**”

“The auditor did **not see objective evidence** that the Food Defense Plan was not challenged.”

How to Be Compliant?

Create Food Defense Team



Identify what you're working with



Conduct Threat Assessment



Develop Preventative Strategies



Create Action Plan



Conduct Self-Assessment/Records

#SFC2019

11.2 Construction of Premises and Equipment

Walls, Partitions, Doors and Ceilings

- 11.2.3.1
- Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish, and shall be kept clean (refer to 11.2.13.1).

Floors Drains and Waste Traps

- 11.2.2.1
- Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

Premises and Equipment Maintenance

- 11.2.10.1
- The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented, planned and implemented in a manner that minimizes the risk of product, packaging or equipment contamination.

Dust, Insect and Pest Proofing

- 11.2.7.1
- All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pest.

Equipment, Utensils, and Protective Clothing

- 11.2.9.2
- Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products.

11.2 Construction of Premises and Equipment: What NCs are we seeing?

Floor surfaces were found to be **cracked** at the packaging warehouse and the receiving freezer.

A roof **leak** was observed in product storage/rack area.

Large **holes** were noted in the bulk flour sifter screen which was located between the outside silo and inside hopper.

The ceiling has large **gaps** with patches of concrete missing in the production area.

During the inspection of boxing room#1 was noticed that 2 shovels used for the floors and 2 shovels used for the product were **stored together**.

Review of production equipment during packaging line changeovers observed that packing machine funnels had **temporary tape** applied on outlet ports instead of cleanable caps.

11.2.12 Pest Prevention

11.2.12.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.



11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

11.2.12 Pest Prevention: What NCs are we seeing?

“It was observed, throughout the northern area fifth floor, a large number of live ants (not easily to count), as well as flies in all floors in the process areas.”

“Rodent droppings were observed at the end of the wall in the room. There were no pest control devices located in this room. A bird nest was observed on one of the pipes that was located in the load out area.”

Two decomposed mice were observed outside of rodent traps in the bulk warehouse behind storage racks. Numerous rodent droppings were observed along the metal support beams against the wall of the bulk warehouse.

There was evidence of pest activity noted during the site tour. Unsalted butter in the cooler had signs of nibbling.

“The service reports indicate that 52 bait stations are inspected and there are no records for the other devices (appears to be an error with how the locations are identified). A current pest control map was not available and did not match the service records.”

11.2.13 Cleaning and Sanitation

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to:

- i. What is to be cleaned;
- ii. How it is to be cleaned;
- iii. When it is to be cleaned;
- iv. Who is responsible for the cleaning;
- v. Methods used to confirm the correct concentrations of detergents and sanitizers, and
- vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.



11.2.13 Cleaning and Sanitation: What NCs are we seeing?

Evidence:

- Equipment cleaning has **not been adequately implemented**
- Residual powder left over on equipment **causing a build up**
- **Overflowing** trash
- Heavy **dust** accumulation
- Significant amounts of **product build up**
- Plant does **not have a master sanitation plan**
- Plant had major build up of product and dust, cigarette and pepsi bottles strewn, **many loose items near product**
- **Black mold** noted in the mixer



11.4 Personnel Processing Practices

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:

- i. Personnel entry to processing areas shall be through the personnel access doors only;
- ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required;
- iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required and off the floor;
- iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate;
- v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2;
- vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food;
- vii. Hair restraints are used where product is exposed.

11.4 Personnel Processing Practices: What NCs are we seeing?

According to floor interview and visual inspections in tour, were observed some **inconsistencies of GMP** (for example, in tour, was observed lack brush in washing rack room, dirty nails with some workers).

During the inspection of the boxing room#1 was noticed that 4 Employees did **not wear their beard-nets** while working in the room.

A roll up door was **left open and unattended** by the mail person, while she was going to pick up the packages that were going in the mail. One wash down hose was observed **stored on the floor**.

The auditor observed that 2 rolls of food contact packaging was **stored directly onto the floor** (the bottom roll was encased in plastic).

An employee working on second shift (graveyard) was found **chewing gum** while working on the bun line in packaging.

11.7 Foreign Object Detection

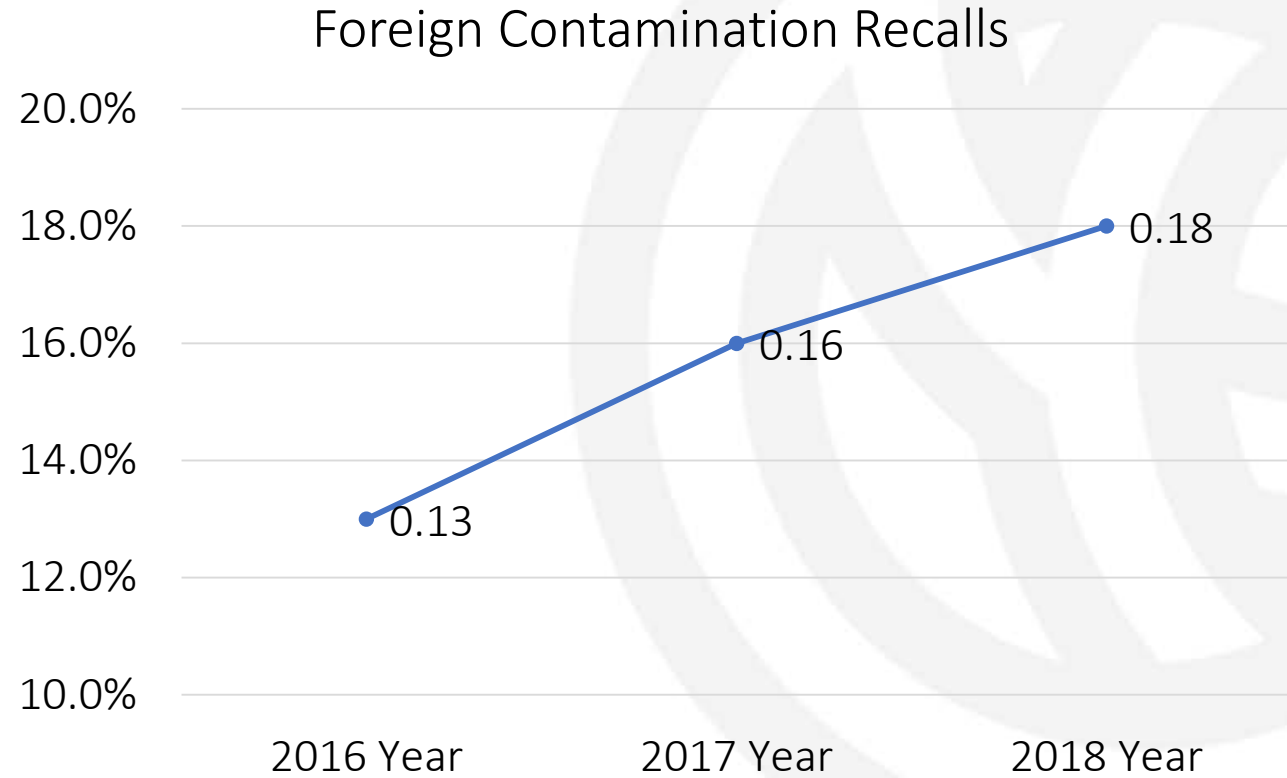
11.7.6.2 (Detection of Foreign Objects) Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.



“The whole ham metal detector **failed** when the 8mm Stainless steel test piece was placed in the centre of the pack and in the least sensitive area of the machine.”

“Metal detector No.3 located in room No.1 **failed** to pick up the 2.5mm ferrous test piece three times during the production and metal detector verification on 13/08/2018.”

Let's Dig Deeper...



My Five Takeaways

1. Conduct Internal Audit...Properly
2. Get Help
3. Stalk food recalls- know the why
4. Day-to-day activities done right make a huge difference
5. Management commitment-be the change you wish to see at your site

2019 SQF Conference



THANK YOU!

SQFI Technical Contacts

North America:

Robert Garfield
Sr. Vice President, SQFI
rgarfield@sqfi.com

LeAnn Chuboff
Vice President, Technical Affairs
lchuboff@sqfi.com

Kristie A. Grzywinski
Senior Technical Manager
kgrzywinski@sqfi.com

Jeanette Litschewski
Technical Affairs Specialist
jlitschewski@sqfi.com

General Info:

info@sqfi.com

Australia, Asia:

Bill McBride
Asia Pacific Representative
bmcbride@sqfi.com.au

Canada:

Frank Schreurs
Canada Representative
fschreurs@fmi.org

México:

Luis Alberto Cruz
Representante en México
lcruzg@consultant.com