

Are You Overlooking Physical Hazards in Your Hazard Analysis?

Session 7:

**Dr. Craig Henry, Intro Inc.
Food Safety Summit, May 2017**

Key Topics

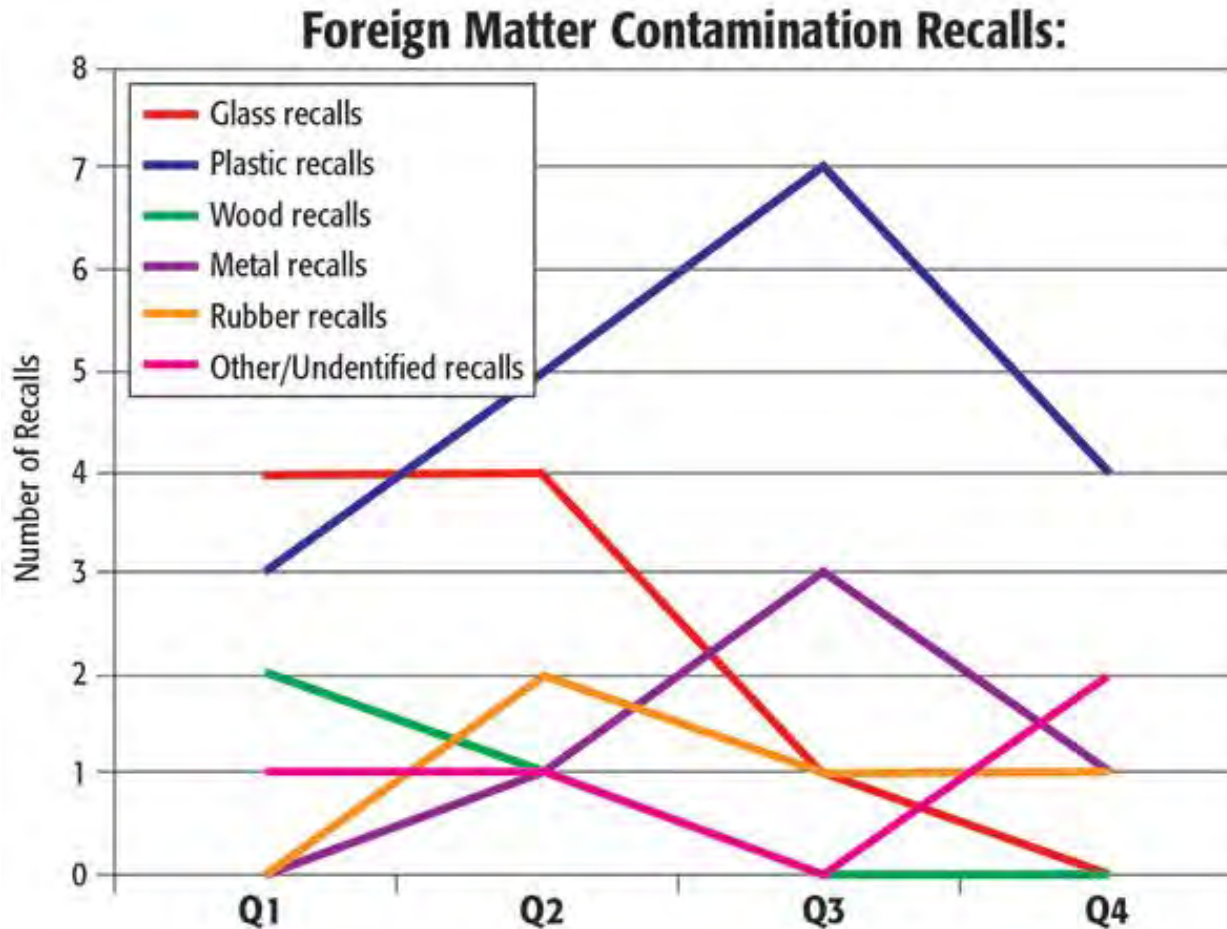
- 1. Food Recalls for Physical Hazards – Lessons learned?**
- 2. Review of Basic Foreign Material Management**
- 3. Harnessing Current Technology**
- 4. Foreign Material Management Challenges**
- 5. Key Industry Considerations**

A Look Back at 2016 Food Recalls

ENEWSLETTER|February 7, 2017: Food Safety Magazine

By Tiffany Maberry

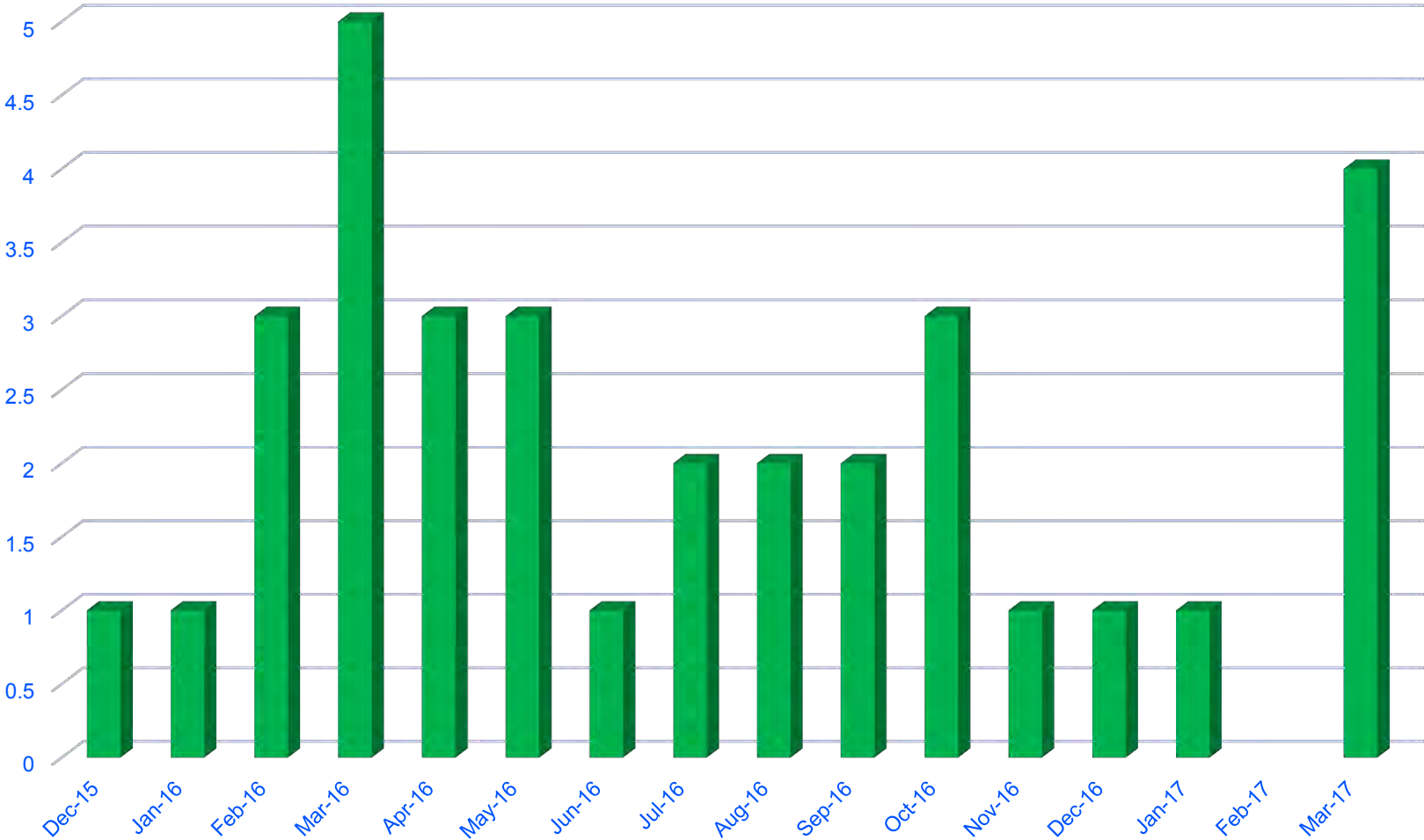
http://www.foodsafetymagazine.com/enewsletter/a-look-back-at-2016-food-recalls/?emailaddress=donna.newman%40fda.hhs.gov&source=govdelivery&utm_medium=email&utm_source=govdelivery



- Note Plastic dominates FM recalls in 2016
- Foods affected by these recalls included everything from meat to fruit to ice cream.
- What do these recalls mean?
- One on hand, it could be a sign that more food companies are investing in the right tools (metal detectors, X-ray machines, etc.) to detect contaminants.
- But it could also be quite the opposite-- food processing mistakes are occurring more frequently.

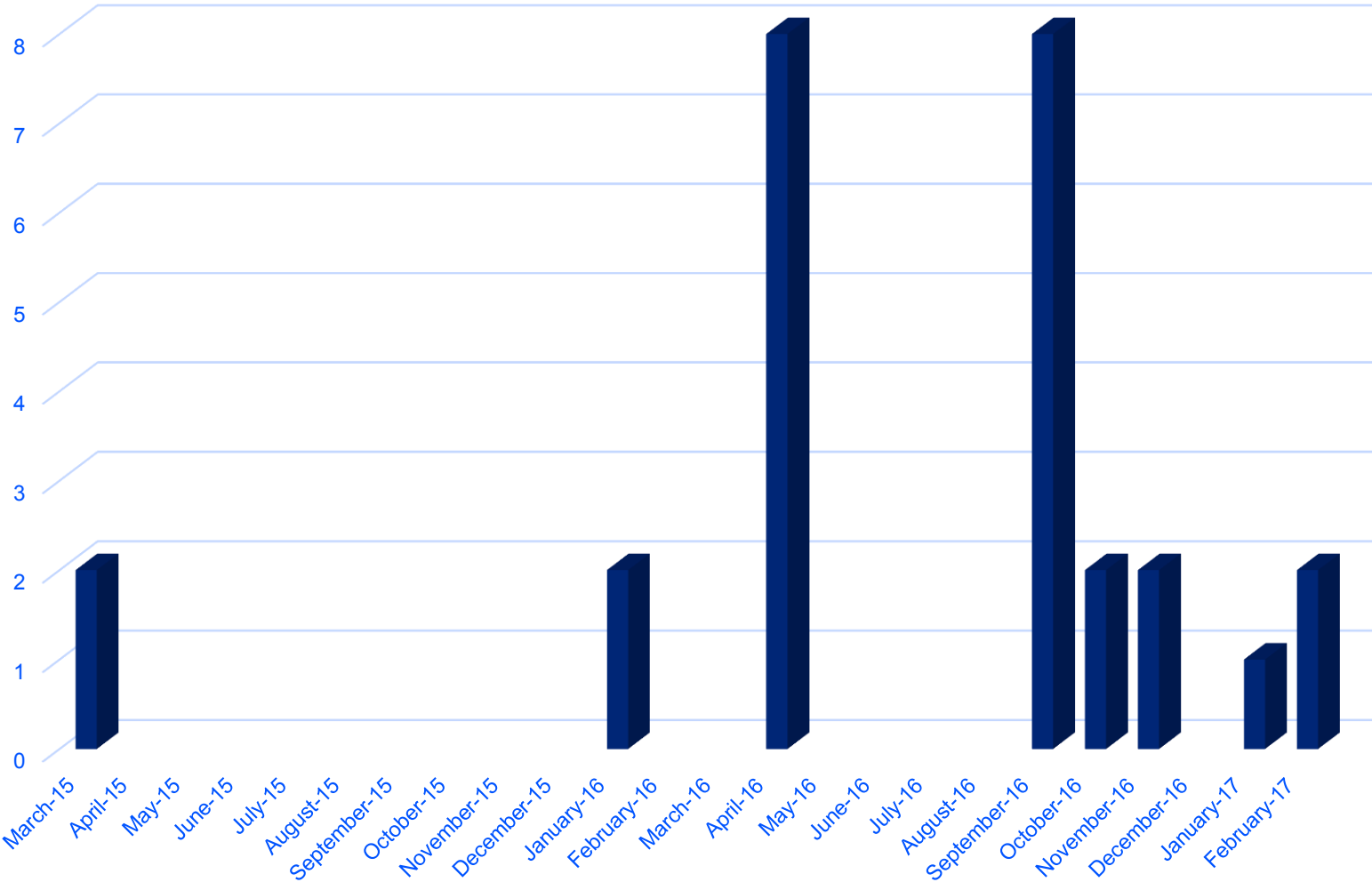
2016- March 2017 USDA Foreign Material Recalls

USDA Foreign Material Recalls



2016- March 2017 FDA Foreign Material Recalls

FDA Foreign Material Recalls



METAL FRAGMENTS CAUSE RECALL OF ALMOST 1 MILLION POUNDS OF CHICKEN

BY [NEWS DESK](#) | MARCH 24, 2017

- The **consumer complaints** began coming in on March 21, 2017 .
- The ready-to-eat (RTE) **breaded chicken** items were produced on various dates from Dec. 19, 2016 through March 7, 2017.
- Contaminated with **extraneous materials**
- <http://www.foodsafetynews.com/2017/03/metal-fragments-cause-recall-of-almost-1-million-pounds-of-chicken/#.WPjTZ4grKUK>



17 AND HALF TONS OF JOSE' OLE' BEEF TAQUITOS RECALLED FOR “EXTRANEOUS MATERIALS”

BY NEWS DESK | MARCH 24, 2017

- **Two consumer complaints** of foreign material in its ready-to-eat beef products on March 14 and 21.
- **35,000 pounds** of frozen ready-to-eat beef taquito products that consumers have said are contaminated **rubber and plastic**
- <http://www.foodsafetynews.com/2017/03/17-and-half-tons-of-jose-ole-beef-taquitos-recalled-for-extraneous-materials/#.WPjTglgrKUK>



MEATBALL RECALL FOR METAL FRAGMENTS EXPANDED TO ALMOST 32 TONS

BY NEWS DESK | MARCH 17, 2017

- Approximately **63,252 pounds of ground beef products** that may be contaminated with extraneous materials
- Several **consumer complaints** stating that **metal objects** were found in the beef products
- <http://www.foodsafetynews.com/2017/03/meatball-recall-for-metal-fragments-expanded-to-almost-32-tons/#.WPjVx4grKUK>



RECALL OF BAD BURRITOS “WITH EXTRANEIOUS MATERIALS”

BY NEWS DESK | MARCH 17, 2017

- **8,622 pounds of frozen burrito products** late Thursday that may be contaminated with extraneous materials, specifically **hard clear plastic**
- **FSIS was notified by the company of three consumer complaints** that were received on March 2, 3 and 9, 2017.
- <http://www.foodsafetynews.com/2017/03/recall-of-bad-burritos-with-extraneous-materials/#.WPjWg4grKUK>



Chapter 5

CHEMICAL, PHYSICAL AND ECONOMICALLY MOTIVATED FOOD SAFETY HAZARDS

Physical Hazards

- Foreign objects
 - Glass and brittle plastic
 - Cuts, choking; may require surgery
 - Metal
 - Cuts, broken teeth; may require surgery
 - Wood and stones
- Choking hazards for young children

Choking Hazards for Young Children

- Small windpipe, underdeveloped swallowing and chewing increase choking risk
- Cylindrical and compressible foods present greatest risk
- No standards for foods but “small-parts test fixture” used for toys

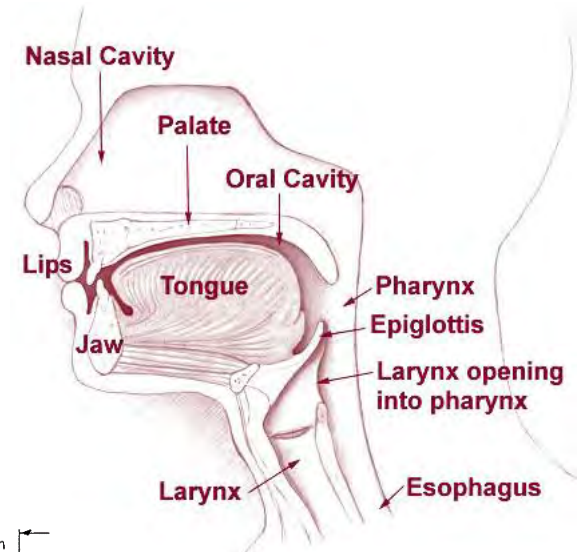
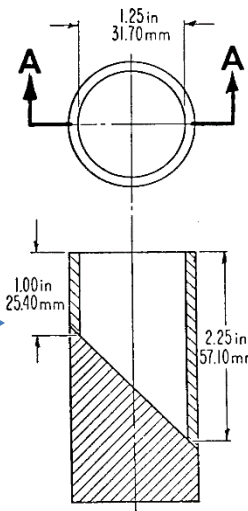


Image from National Cancer Institute



Section A-A

Image from Consumer Products Safety Commission

Prevention based on HISTORY and IMPROVEMENTS

- ✓ Manufacturing facilities must review their production history and work closely with maintenance to record any findings of foreign material risk.
- ✓ Consumer complaints as evidence in prior recalls continue to be a very good source of hazards found within finished product.
- ✓ Under FSMA the PCQI is responsible for updating and revising the facility's food safety program based upon new findings or guidance.
- ✓ FDA expects the PC Food Safety Program to be a DYNAMIC EVER EVOLVING DOCUMENT.
- ✓ Therefore it should be clearly evident that continuous changes are made and the preventive controls improved to show a decline in the risk to the public and the company.

Review of Basic Foreign Material Management

Physical Hazards

GLASS



METAL



STONES



Regulatory Guidance

FDA Compliance Policy Guide, Section 555.425 “Foods - Adulteration Involving Hard or Sharp Objects.”

- Ready-to-eat foods containing hard or sharp foreign object 7-25 mm in length

USDA/FSIS guideline

- 2 cm or 0.8 inch for choking hazard, but it also depends on target consumers (e.g., smaller size for food intended for school lunch)
- FSIS Directive 7310.5 provides guidance to inspectors on foreign materials; no specific size guidance for physical hazards

Sources of Physical Hazards

- Contaminated raw materials
- Poorly designed or maintained facilities and equipment
- Faulty procedures during production
- Improper employee practices
- Processing/operation with metal contacts
 - e.g. grinding

Food Safety vs. Aesthetics

Potential physical hazards are foreign objects or extraneous matter capable of causing injury, e.g. glass, metal, rocks.

Aesthetic contaminants such as insect fragments, hair and sand typically do not cause injury to consumers.

- **A contaminant in a product represents a physical hazard if it will result in injury to the consumer.**
- **(Usually hard, sharp objects between 7-25 mm.)**

Minimizing Physical Hazards - Employee Practices

▪ Adherence to cGMPs

- proper outer attire, no jewelry, no pens in outer pockets

▪ Employee training

▪ Control maintenance work

- Inspect work areas for loose hardware and tools.
- Clean/inspect lines prior to restarting operations.
- Reconcile tool and parts inventory.

Controlling Physical Hazards During Processing

Identify potential sources

- Metal, glass, etc.

Implement programs to minimize likelihood or control the hazard

- Glass breakage program, metal detection, etc.

Equipment Used to Detect or Remove Foreign Materials

- Magnets / metal detectors
- Screens / sifters
 - More focus on this type of preventive control in light of recent recalls for foreign material in flour.
- Aspirators
- Flumes
- Bottle / can cleaner

Harnessing Current Technology

Advanced Detection Technology for Food Processing Lines

Yang Tao, Ph.D, P.E.



University of Maryland
Bio-Imaging & Machine Vision Laboratory

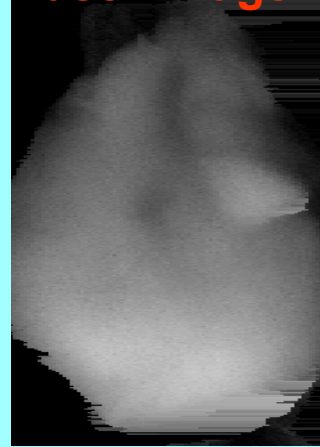
Seminar at NFPA, Washington DC, **11/17/2004**

(3) X-ray & Laser Sensor Fusion

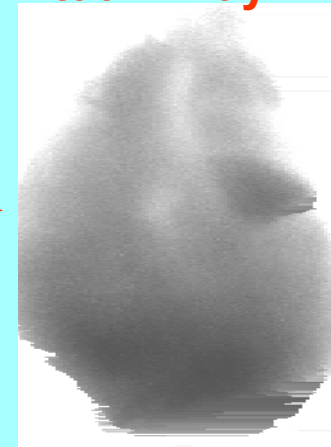
X-ray Image



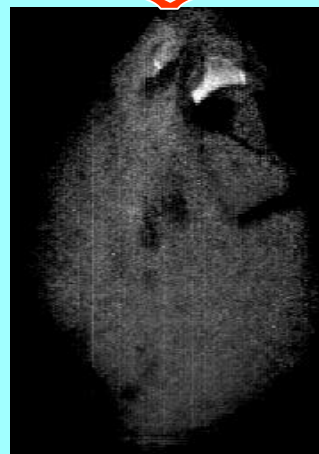
Laser Image



Virtual X-ray Image



Thickness Compensated



Combined Image



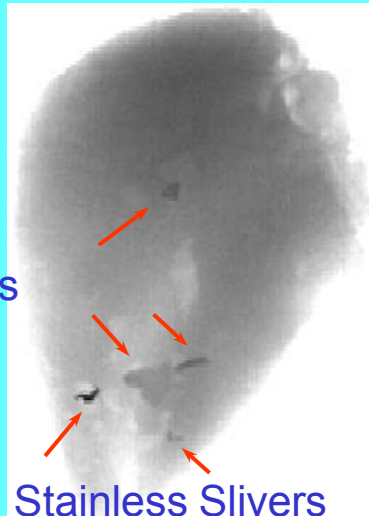
Stainless Steel Fragment
+ Fan bone

Fragments



Laser

X-ray



Mapped

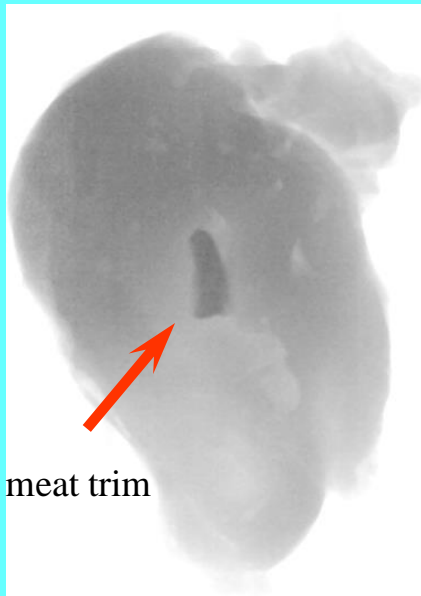
Combined



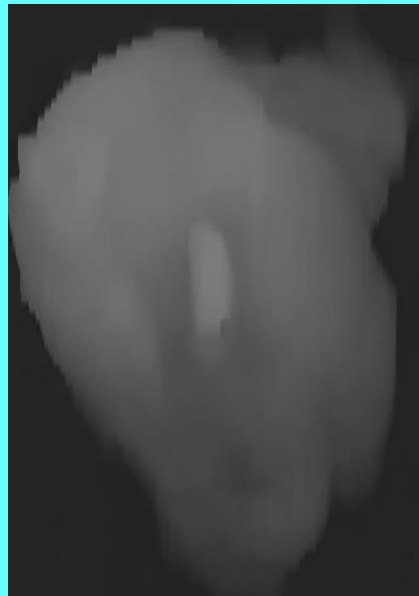
Extracted

X-ray & Laser Imaging

X-ray Image



Laser Image

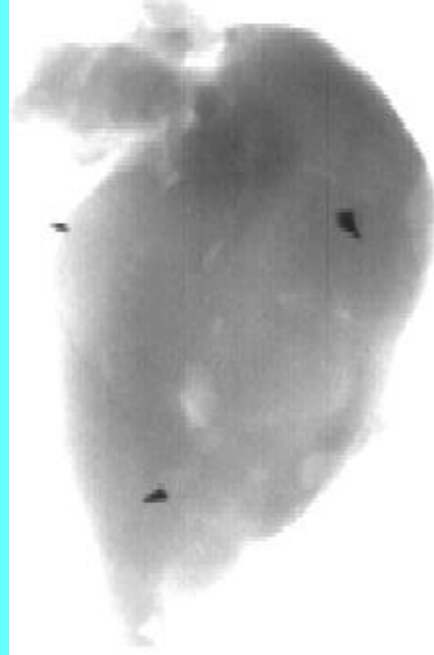


Result Image



Not achievable by x-ray imaging alone or conventional techniques

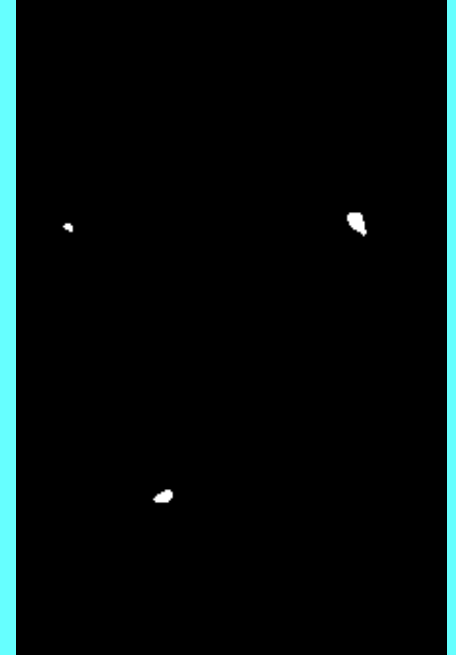
Glass fragments



X-ray Image



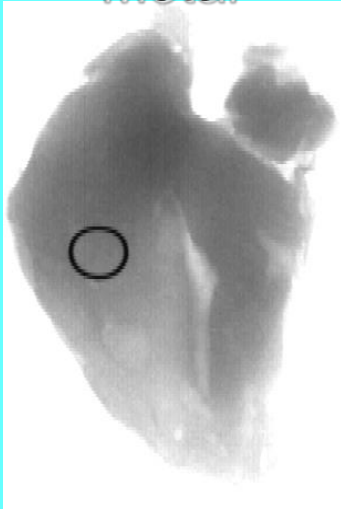
Laser Image



Extracted

Other Contaminants (easy)

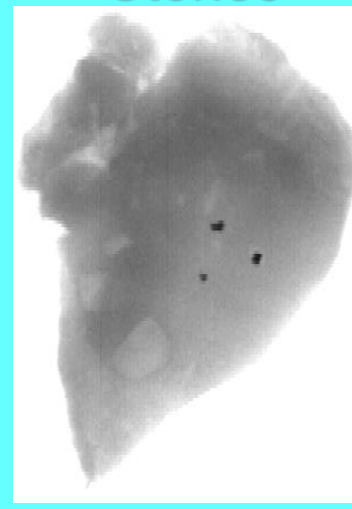
Metal



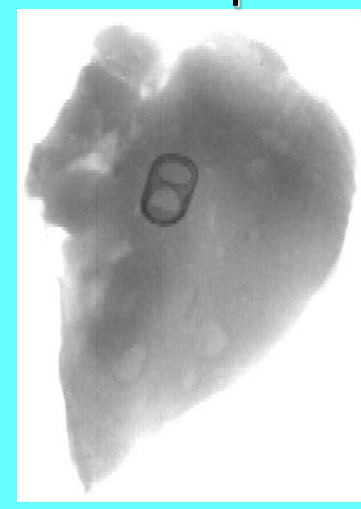
Fallen
Parts



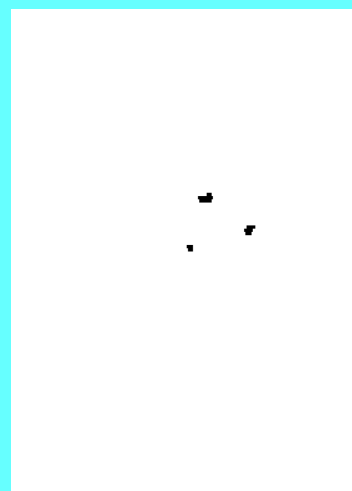
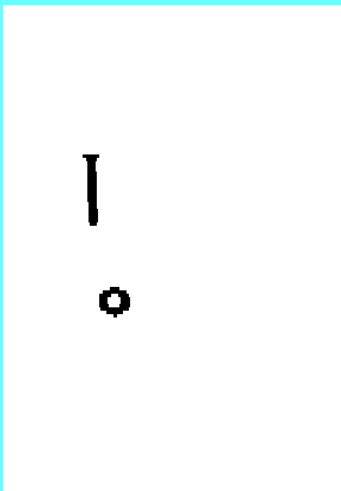
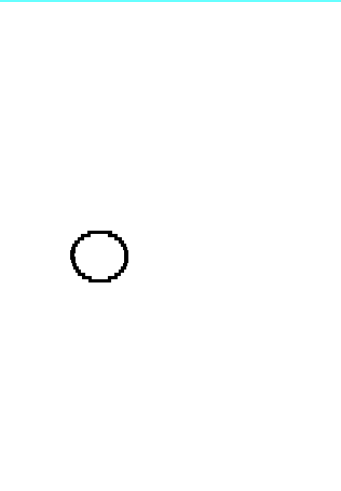
Stones



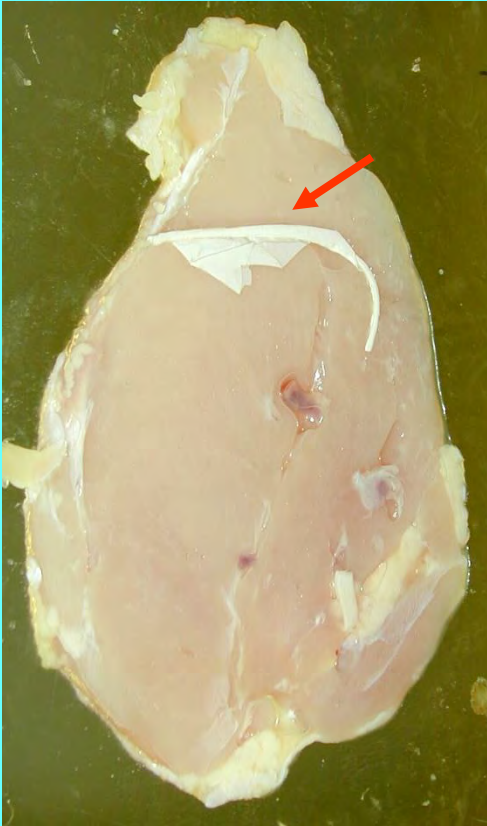
Can Cap



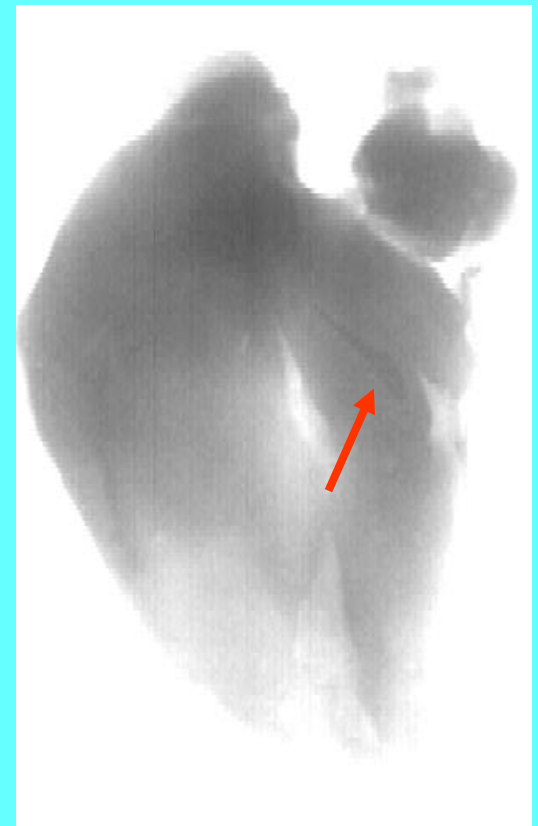
Extracted:



Rubber and Wood Pieces (not easy)

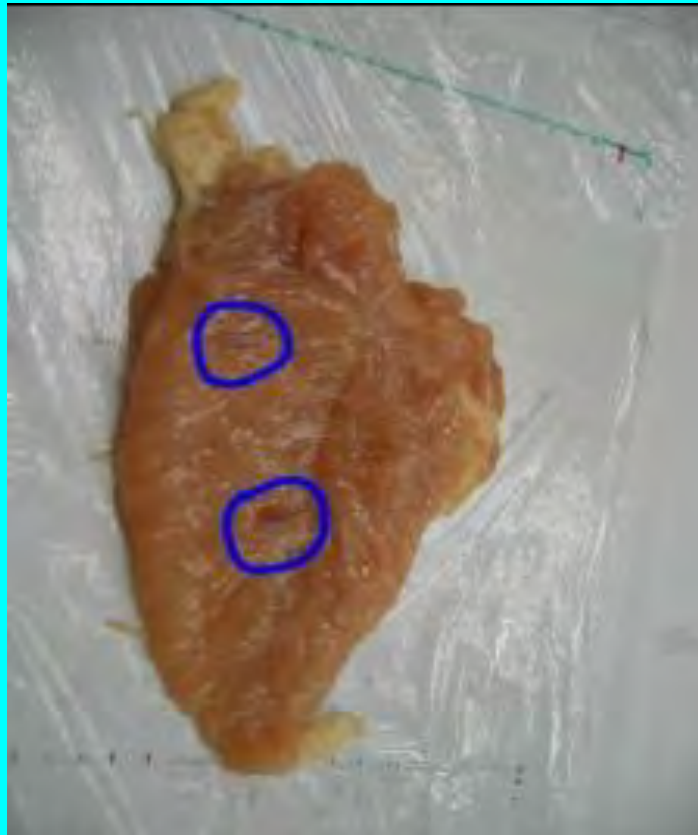


Glove Rubber
(other kinds to be checked)

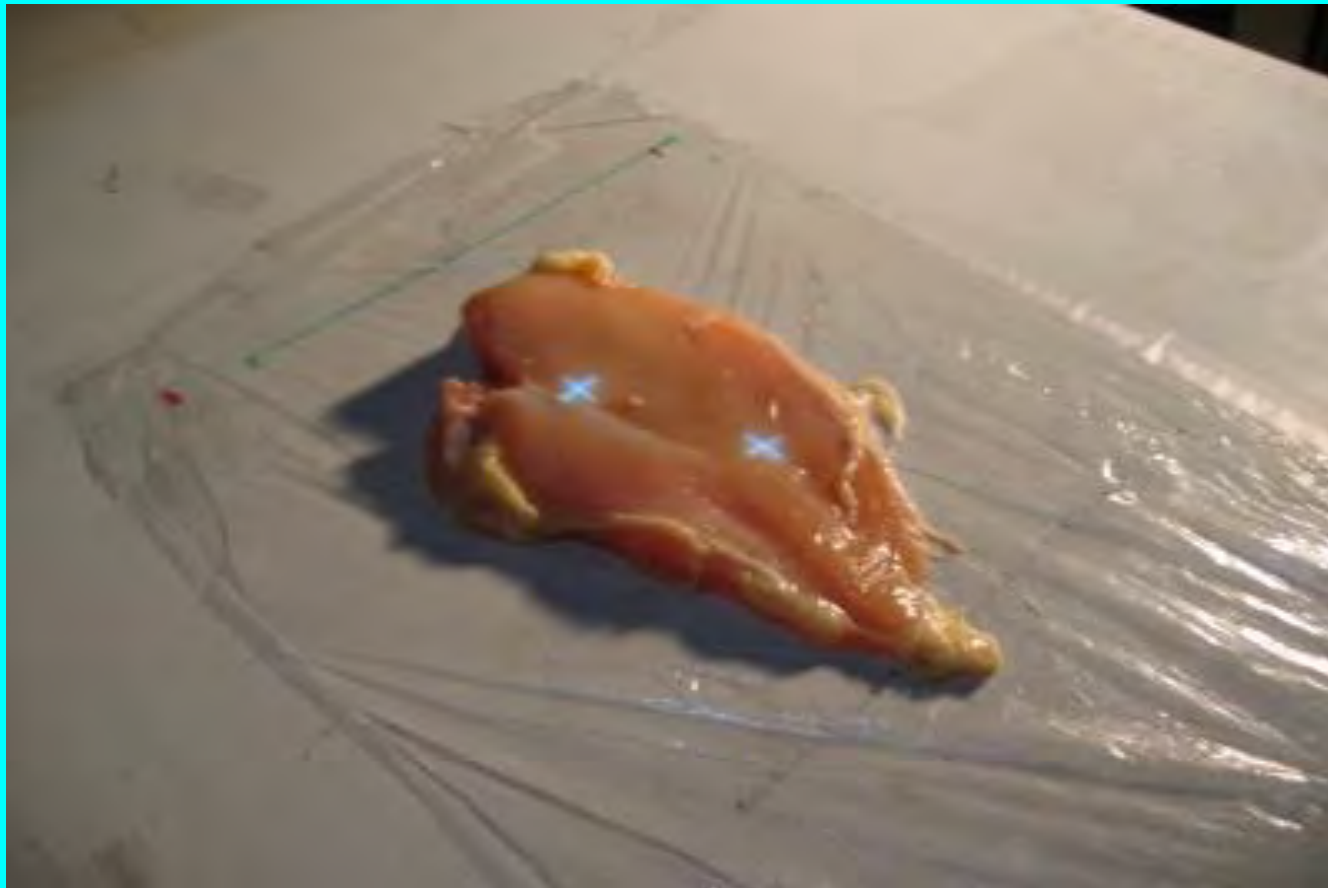


Wood Chip

Pin-point Hazardous Items



“Pin-point” detected items on-line





Machine 1

2017

LaXser for Detecting Bones X-ray + 3D Laser Imaging



LaXser Imaging Bone Fragment Detector



Chicken sandwiches are good,

But bone fragments can choke small children & the elderly

Chicken De-boning Operations

- **40 Billion Lb / yr – U.S. (USDA)**
- **48% for Boneless Meat**
- **Ready-To-Eat Products**
- **Convenient to Consumers**





Bone fragments in fillets must be detected & removed to prevent the danger from choking small children and the elderly.

LaXser Imaging Detection System

Industrialized Food Quality & Safety Inspections for Bones and other Objects



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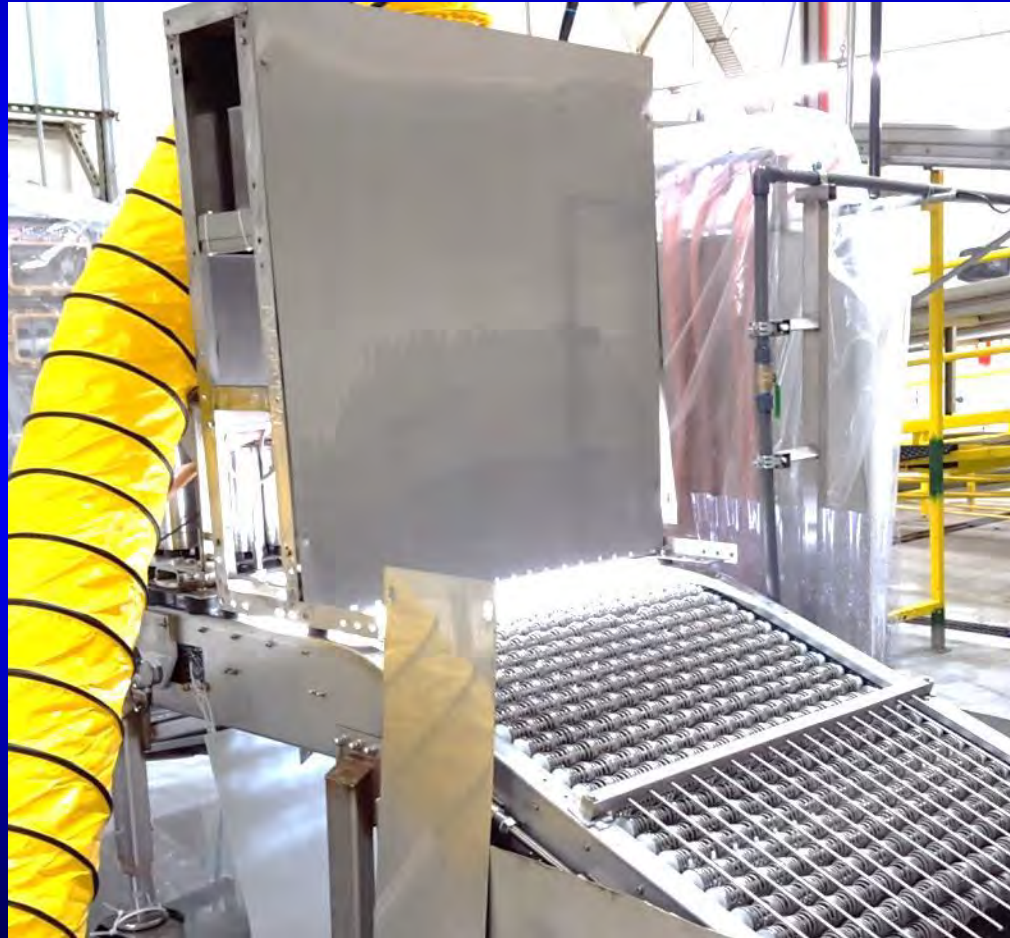


Machine 2

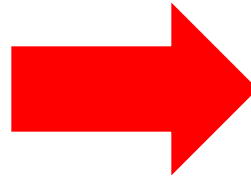
Patented

AVID

Automated Vision Intelligence De-Calyxer



Strawberry Ice Cream or Cereal?



Stem and Crown leaves are inedible
So, how are they removed for ice cream and cereals?



Old (current) Way



Field harvester is cutting strawberry crowns using blades. It is labor insensitive and dangerous in finger laceration.



Summary

Automated Vision-Guided Machines can Improve the Productivity, Food Quality & Safety, and Profit through Labor Savings and Adding Values to Products.

Labor Intensive



Automation



Contact: Dr. Yang Tao, Tel: 301-405-1189, ytao@umd.edu

Foreign Material Management Challenges

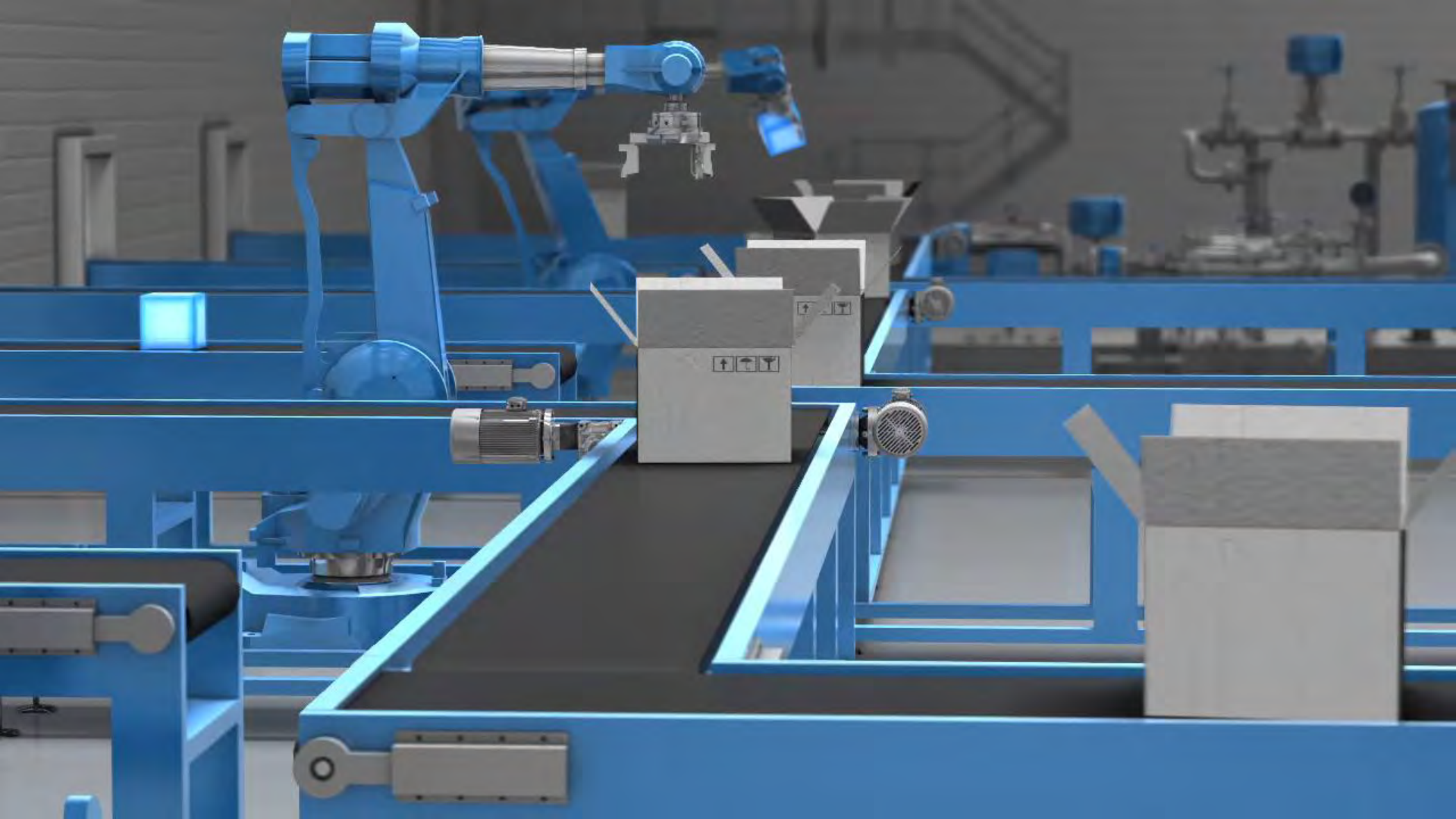
1. Equipment is expensive and technology is ever changing
2. Management must be prepared to embrace new technology as dictated by risk to consumers and the company
3. Equipment manufacturers **MUST** be evaluated for the long-term support required to maintain, verify and validate process efficacy.
4. Staff turn-over continues to be a huge challenge for all facilities.
5. However, human resources must be engaged to help ensure critically trained staff supporting the equipment and processes remain as part of the team long term.
6. Continuous staff turn-over is expensive and increases the chance of major mistakes affecting the company but more importantly the consumer.
7. Such mistakes can lead to in-depth **INVESTIGATIONS BY REGULATORS.**

Key Industry Considerations

1. **Protect the Public** – Primary task is to protect the public first
2. **Protect the Brand** – Secondary task is to protect the brand.
3. **Regulatory Expectations** – FDA, USDA and industry will learn together during inspections. PREVENTION is the focus and requires active and OBVIOUS management.
4. **Embrace strategies rigorously** - Based upon written programs, industry must focus more heavily on DOCUMENTATION to establish a valid food defense plan to present during an inspection.
5. **Response** – As many facilities conduct mock recalls, and evaluate internal verification and validation of processes the goal is to FIND THE PROCESS GAPS.
6. **Recover** – Be prepared to COMMUNICATE internally and externally with legal counsel involved, at a moments notice so proper actions are taken.
7. **Supplier and Facility Audits** – Trust third party audits but verify!!

Thank you

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Factory Assessments

Physical Hazards

SESSION OUTLINE



- Exclusion Controls Overview
- KEY FDA Guidance Points
- Hard Look at Metals
- Gaps and Pitfalls



Physical Hazards - Foreign objects

A wide range of equipment is used to remove foreign materials, including:

- Metal Detectors
- Magnets
- X Rays
- Sifters/strainers
- Filters/screens

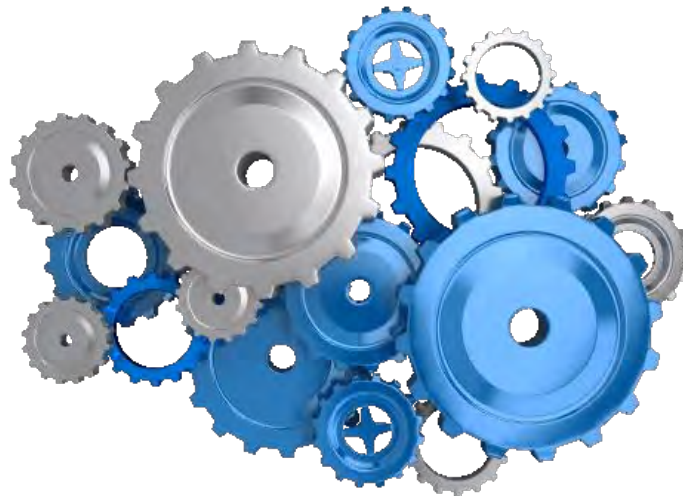


FDA GUIDANCE ON METAL

Metal-to-metal contact during processing can introduce metal fragments into products.

Examples,

- metal fragments can break off during mechanical cutting and blending operations,
- metal equipment with parts that can break or fall off, such as wire-mesh belts.



FDA GUIDANCE ON METAL

FDA has supported **regulatory action** against products with metal fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length.



Such fragments have been shown to be a hazard to consumers.



Process Control for Metal Detection

Critical Limits:

- ✓ Metal detector present and functioning
- ✓ No metal present in product* that has passed through the detector
- ✓ Visual monitoring that kick out/reject is working



- *that would cause choking or injury

Process Control Records

“Exclusion” Process Control

- ✓ Monitoring
- ✓ Corrective Actions
- ✓ Verification
- ✓ Validation...?



Monitoring for Metal Detection

WHO/WHAT Production staff - All product passes thru a detector

WHEN Start, middle and end of shift

HOW Visual examination that the detector is on and reject device is working

Work Instructions should clearly describe test sample placement for the product type/size of package.



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Corrective Actions

If product is processed without metal detection:

- Hold until passed through metal detection
- Correct operating procedures to ensure that the product is not processed without metal detection.

If metal is found, segregate product, and

- Inspect back to the last good check, rework or discard product depending on metal type and prevalence.

Identify source of the metal and correct the cause of the contamination;

- > fix the damaged equipment, or
- > discard and replace with better design

Recorded Corrections/Test Failures

Re-running product through a functioning metal detector when a unit fails a test sample verifies that the metal detector was operating correctly, because

- It provides a record of the problem and,
- Describes the steps taken to correct the problem.



- FDA Draft Guidance for Industry



Operational Verification

Pass **X** mm ferrous and **Y** mm nonferrous and stainless standard wands through detector

- at start-up,
- middle and
- end of shift, and
- whenever product changes occur on the line to assure equipment is functioning.

Review of Metal Detector Log and Corrective Action and Verification within 7 working days.

FSPCA: **X** and **Y** values are determined during calibration

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Metal Detector Calibration

FDA Guidance: monitoring may be limited for measures such as preventive maintenance on equipment to prevent metal hazards. Keep a record that the activity took place!

- *Calibrations are a required verification activity for the instruments used for monitoring. Metal detector adjustments vary with age and brand, contact the manufacturer for advice.*

Calibration Data Example:

- Date of Calibration
- Equipment ID or Line Number
- Method of Calibration
- Calibration Results: Adjusted-Passed and/or Failed, requires repair)
- Results within Specification (Yes/No)
- Internal maintenance or outside contractor sign off



"I believe the test wand is placed on the package like this..."



"I agree with you, but check the SOP!"



Sample placement should be determined according to the manufacturers instructions.

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Records

- Metal Detector Log
- Corrective actions records
- Manufacturer's **Validation Study** that determined detector settings and sensitivity standards

VALIDATIONS - GAPS AND TRAPS TO AVOID



GAPS –

- Verification with the wand is not validation
- Contact the manufacturer to arrange calibration



TRAP

- Wand placement varies based on multiple factors
- Auditors typically assess the wand/reject process



Assessing Metal Hazards in Food Production

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Metal in the Food Facility

The industrial environment relies heavily on the durability and flexibility of metal

- Metal parts that wear over time becoming thin and fragile
- Removable nuts bolts screws etc., that can work loose
- If it can happen, it will!



Physical Hazard Controls

**AUDIT
CRITERIA**



Equipment Design and Use

Will the equipment provide the time-temperature control that is necessary for safe food?

Is the equipment properly sized for the volume of food that will be processed?

Is the equipment reliable or is it prone to frequent breakdowns?

Is the equipment designed so that it can be easily accessed, cleaned and sanitized?

Is there a chance for product contamination with hazardous substances; e.g., glass, plastics?

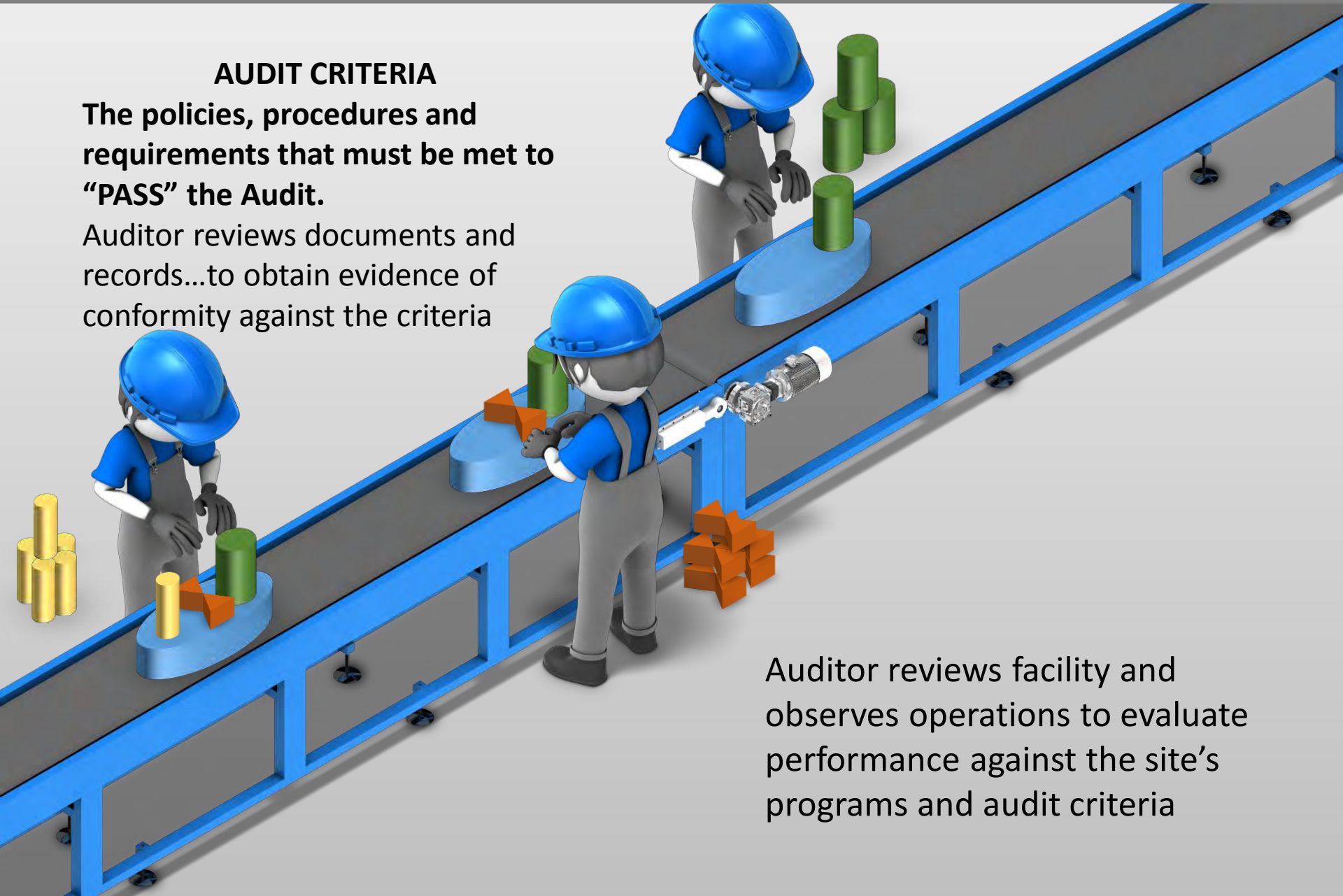
Where data is available, does certain equipment have a history of issues?

PREVENTIVE CONTROLS FOR PHYSICAL HAZARDS

AUDIT CRITERIA

The policies, procedures and requirements that must be met to “PASS” the Audit.

Auditor reviews documents and records...to obtain evidence of conformity against the criteria



Auditor reviews facility and observes operations to evaluate performance against the site's programs and audit criteria

Foreign Material Prevention

Audit Criteria

The responsibility and methods used to prevent foreign material contamination....

Inspections to ensure plant and equipment remain in good condition.

Loose metal objects on equipment, shall be removed or tightly secured

Knives and cutting instruments shall be controlled, clean and maintained.

Separate Criteria for Glass, Wood and Plastics

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Foreign Material Detection

Audit Criteria: The responsibility, methods and frequency for

Monitoring, maintaining, calibrating and using technologies to remove or detect....

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



General Criteria

Calibrations in the regulation and audit criteria

- **Specifications** for equipment, and procedures for purchasing
- **Calibration methods-** responsibility for measuring, testing ...shall be documented and implemented.
- Equipment shall be calibrated against reference standards and/or method to accuracy appropriate to its use.
- ...where standards are not available,
 - evidence to support the calibration reference method applied must be provided.
- Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.



General Criteria

Calibrations in Audits

- Equipment shall be calibrated against reference standards and/or method to accuracy appropriate to its use.
- ...where standards are not available,
 - evidence to support the calibration reference method applied must be provided.

Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.



Audit - Regulation Comparison

NEW AUDIT REQUIREMENT: PROCESS FLOW EXPANDED

The process flow shall be **designed** to prevent cross contamination and **organized** so there is a continuous flow of product.

The flow of **personnel** shall be managed such that the potential for contamination is minimized.

How to audit these points?

PC REGULATORY REQUIREMENTS

LITERAL:

NO stated requirement
“process flow”

Implied:

“Recommended”
per HACCP Prelims

Conferred:

117.126 Hazard Evaluations:

The condition, function, and design of the facility and equipment;

Documented where?

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Questions?

