

2021

The Meat & Poultry
Industry

Foreign Material Manual

CONSIDERATIONS FOR DESIGNING A
FOREIGN MATERIAL CONTROL & PREVENTION
PROGRAM





“

OUR GOAL
IS TO REDUCE THE
OCCURRENCE OF
FOREIGN MATERIAL
IN MEAT & POULTRY
PRODUCTS.

”

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1



DESIGNING A
**Foreign Material Control
& Prevention Program**
(FMCPP)

1

PART ONE

Designing an FM CPP

This manual is a comprehensive compilation of information for establishments to consider when designing a Foreign Material Control & Prevention Program (FM CPP)

It covers the entire process in three main sections: **prevention, detection, and response**. Not all of the information will apply for every operation and each establishment should assess which aspects may apply to its operation.

It is important to design a FM CPP that is specific to the establishment. The success of a FM CPP hinges upon a supportive culture where the entire company is encouraged to voice and address concerns. A FM CPP may be one comprehensive program or the combination of multiple individual programs.

Although this manual is designed to be comprehensive, the purpose is to aid in the development of establishment specific FM CPPs and it is not all inclusive. Establishments may utilize information or implement methods not covered in this manual. This document is not intended to set industry standards or to be used as an indicator of best practices.

WHAT IT IS...

- Comprehensive
- Considerations
- Reference

WHAT IT ISN'T...

- All-encompassing
- Best Practices
- Guideline

Note: Although this document is not designed to address intentional adulteration, some aspects may be applied for that purpose.¹

¹ Resources specific to intentional adulteration:
FSIS Food Defense Tools & Resources:
<https://www.fsis.usda.gov/food-safety/food-defense-and-emergency-response/food-defense>
FDA Food Defense Tools & Resources:
<https://www.fda.gov/food/food-defense>

DEFINITION OF **Foreign Material**

FMCCP

As it pertains to this manual, foreign material refers to extraneous materials that are not intended to be in product and not inherent to the animal such as:

- metal
- plastic
- glass
- fabric
- string
- rubber
- human hair
- wood

Although this manual is not designed to cover materials inherent to the animal, such as hair, feather, or bone, these materials are mentioned for informational purposes when elements of the manual may help establishments in developing a program to control these materials.

Foreign material will be abbreviated as FM throughout the document.



Risk Assessment

When developing a **Foreign Material Control & Prevention Program (FM CPP)**, each establishment should begin with a risk assessment.

Although a risk assessment is inherent when conducting a hazard analysis for a HACCP Plan, a FM CPP will likely cover all foreign material where a HACCP Plan may only address foreign materials that present a food safety hazard.

Risk assessments can be broken up into multiple assessments using one or more methods or one comprehensive assessment, but all aspects of the operation must be considered:

- **people**
 - **environment**
 - **equipment**
 - **raw materials**
 - **packaging**
 - **chemicals**
 - **sanitation**
- and any other potential vectors that might be applicable to a facility. Through the risk assessment, the establishment will be able to determine potential vulnerabilities and can determine whether methods for prevention, detection, or both are appropriate.

When assessing risk, it is important to evaluate the likelihood and severity.

Historical data may demonstrate the likelihood of various types of FM to be introduced at certain steps. Understanding whether and how often incidents have occurred before can inform and support decisions on FM risk. More information on implementing a program to track and trend FM incidents can be found in the response section.

These data should be examined to determine whether a prediction can be made about the current system.

However, data integrity is key. If incidents have not been properly and consistently identified and recorded, the data will likely not be adequate for use in a risk assessment.

For example, if significant changes were made to improve the identification and recording of incidents, what seems like an upward trend in incidents may just be an increase in well-documented incidents and not a reflection that more incidents are actually occurring.

Historical data might be useful in determining the severity, but more often severity is determined by an evaluation of the types of FM that may be introduced, the amount of product that might be involved, and any vulnerabilities based on the product type, such as products for high risk consumers or ready-to-eat (RTE) products.

The next step in the supply chain, product use, and the end consumer are key pieces of the puzzle.

Risk assessments should be reevaluated as needed when there are significant changes to the process, products, incoming materials, vendors, or other aspects, or in response to an incident (see Response Section).

Risk Assessment Types

Risk assessment can generally be divided into two categories:

Qualitative:

A series of questions to determine risk. This method is similar to the hazard analysis process companies currently use for their food safety systems.

Quantitative:

A scoring system to determine risk. A numerical value is assigned to various levels of likelihood and severity. The values are combined to assign an overall risk level within the risk matrix.

EXAMPLE OF QUALITATIVE RISK ASSESSMENT:

Has the material caused a FM incident before?

- If no, the company may choose to utilize this as support for a low risk.

If the answer is yes, other questions should be asked, such as:

- How often has this happened? Is it frequent?
- Is there a common source for the FM?
- Can the FM issue be designed out?
- Is there a procedure the company can perform to prevent FM contamination?

ANOTHER OPTION

Is to utilize a numerical system where risk is subjected to a scoring system.

Scoring is also based on likelihood and severity but a numerical value is assigned to each answer. The values of each answer are combined to assign an overall risk level to aid in determining risk based on where the resulting value falls within the risk matrix.

EXAMPLES OF A QUANTITATIVE RISK MATRIX:

Note: The example matrices were developed by third parties, see the references provided for more information on each matrix. The parameters may not be applicable and establishments may elect to modify one of these matrices, utilize another, or create a matrix.

British Standards Institute Example²

In this matrix the Risk Level is determined by multiplying the points attributed to the Severity Rating, Size Rating, and Likelihood/Probability.

RISK LEVEL

= Severity Rating x Size Rating x Likelihood/Probability

Fig. 1.1
Risk Assessment



² Smith, D, *ISO 22000 Food Safety: Guidance and Workbook for the Manufacturing Industry* (London: British Standards Institute, 2007). A summary of this example can be found at <https://www.foodsafetymagazine.com/magazine-archive1/december-2015january-2016/how-food-companies-can-modify-their-existing-haccp-plans-into-an-all-encompassing-food-safety-plan/#References>.

Severity Rating Guidance

- MINOR: **1 point**
Straw, vine, paper, cardboard, hair, congealed material (soft)
- MEDIUM: **2 points**
Wood, soft plastic or rubber, insects, congealed material (hard)
- MAJOR: **3 points**
Metal, rock, glass, hard plastic, bones³

Size Rating Guidance

- NOT A SAFETY HAZARD: **1 point**
Objects greater than 4.5 cm (1.75 inches)
- MINOR HAZARD: **2 points**
Particles less than 7 mm (0.3 inch)
- MAJOR HAZARD: **3 points**
Objects between 7 mm and 20 mm (0.3 to 0.8 inch)⁴
- CHOKER HAZARD: **4 points**
Objects between 2 and 4.5 cm (0.8 to 1.75 inches)

Likelihood/Probability of Occurrence of Threat

- REMOTE: **1 point**
Chance of occurrence is less than once every 2 years
- POSSIBLE: **2 points**
Occurs at least once every year
- POTENTIAL: **3 points**
Occurs at least once a month
- LIKELY: **4 points**
Occurs at least twice a month or more often

³ Bone is not considered FM in this document; however, it is part of the referenced matrix and is included here to maintain the integrity of the reference.

⁴ US Standards are 7-25mm, see [Response Section](#).

Failure Modes and Effects Analysis (FMEA) Examples⁵

In this matrix the Risk Priority Number is determined by multiplying the points attributed to the Severity, Probability, and Detectability.

RISK PRIORITY NUMBER (RPN) CALCULATION
 = Severity X Probability X Detectability

1-5 RATING SYSTEM

Legend (0-125)
RPN Scale

RPN SCORES

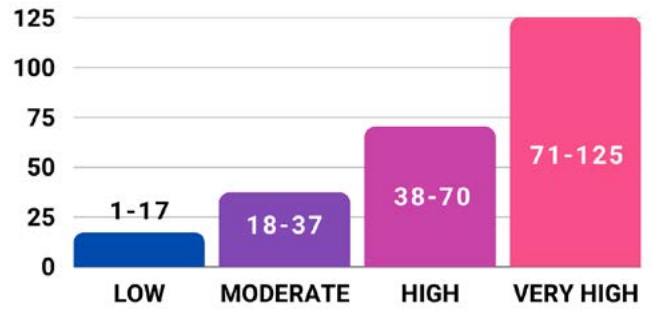


Fig. 1.2
 1-5 Rating System

Rating	Probability	Severity	Detectability
5	0-1 month	Death, Business Closure, Loss of Business	Unable To Detect
4	1-3 Months or Located Over Product Zones	Permanent Injury, Recall, Reduced Business	Very Low
3	3-6 Months or Adjacent To Product Zone	Temporary Injury, Product Hold, Negative Impact with Customer Relationship	Low
2	6-12 Months or Within Exposed Product Processing Room	Complaint, Warning Letter, Customer Response Required	Moderate
1	12+ Months or Outside Exposed Product Handling Area	No Issue	High

⁵ A quick guide on FMEA can be found at <https://www.isixsigma.com/tools-templates/fmea/fmea-quick-guide/>

1-10 RATING SYSTEM

Legend (0-1000)
RPN Scale

RPN SCORES

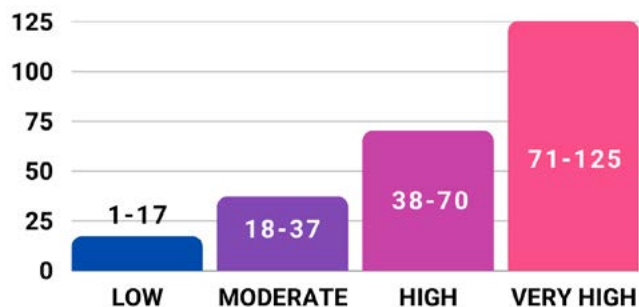


Fig. 1.3
 1-10 Rating
 System

Rating	Severity	Probability	Detectability
10	Death	3-4 times per day or more	Impossible to detect
9	↓	More than once per day	Remote
8	Permanent Injury	Once a week	Very slight
7	↓	Once a month	Slight
6	Temporary Injury	Once in three months	Low
5	↓	Once in half-one year	Medium
4	Reported / Dissatisfied	Once a year	Moderately High
3	↓	Once in 1-3 years	High
2	Notice / No Report	Once in 3-5 years	Very High
1	↓	Less than once in 5 years	Virtually Certain

See **ADDENDUM A** for an example Risk Assessment Form when using a quantitative risk matrix.

Other Risk Assessment Options:

The Food Safety and Inspection Service (FSIS) also published guidance on various risk analyses.

Multi-Hurdle Approach

Informed by the risk assessment, establishments will start to determine the best control methods for the risks identified.

Some of the possible methods will be outlined in the following sections, broadly categorized into methods for prevention, detection, and response.

Depending on the FM risk, one control method may not be sufficient. Establishments should consider the benefits of a multi-hurdle approach.

A multi-hurdle approach may be appropriate where multiple control methods are more effective than one or where FM may be introduced at multiple points in the process. Robust FM CPPs will incorporate multiple control methods where appropriate.

Although there are numerous combinations of control methods, a couple examples of potential multi-hurdle approaches include:

- A processor might utilize a prevention method, such as an approved supplier program, to prevent FM in raw materials, but also use one or more detection methods during processing, such as a metal detector to verify the absence of metal prior to comminuting and an X-ray once the product has been comminuted to detect other FM.
- A slaughterer might employ one or more prevention methods, such as GMPs and a tool tracking program, but also use a detection method during processing, such as a vision system to detect FM in trim.

The risk assessment will drive how many and what type of methods might be implemented and whether a multi-hurdle approach is ideal for the process.

FM CPPs will look vastly different across establishments of different size and access to resources, but the number of controls in place is not an indicator of whether the program is robust. A **single control** may be the best approach for a particular establishment, whereas another may be more successful with several controls used in tandem. More controls do not automatically result in less FM.

Each control method must be appropriate to the product, facility, and FM and be implemented properly.

Validation & Verification

Establishments should ensure the FM CPP is effective and operating as designed.

There are many ways to achieve this goal that typically fall under two categories: validation and verification. Establishments may elect to evaluate the program as a whole or break the individual components or a combination of the two.

Validation

ensures the program or component is capable of achieving the intended result.

Verification

ensures the program or component is being implemented as designed.

Some activities can accomplish both elements.

For example, using a standard to monitor a detection system during operation validates that the detection system is capable of detecting the desired material and verifies that it is functioning as designed. See the calibration section for each detection method for more information on monitoring.

Establishments that decide to address **FM** through the **hazard analysis** will need to comply with regulatory requirements.⁶

Whether a company determines the hazard is likely or unlikely to occur, the regulations require validation to ensure that the program is working as intended.

Once the program is validated, verification activities should be developed to ensure the program continues to operate in a manner that supports the decisions made in the hazard analysis.

⁶ **REGULATORY REQUIREMENTS:** More information on the US requirements for HACCP Validation can be found at <https://www.fsis.usda.gov/guidelines/2015-0011>

The **FM CPP** should be validated upon implementation and following a change to the program. It should be verified on an on-going basis. Frequency of verification will depend on the unique goals of the establishment.

However, establishments should consider that verification provides key support that the system is functioning as designed. In the event of an incident, establishments may utilize verification monitoring to determine scope.

A higher monitoring frequency may result in a smaller scope of potentially impacted product following an incident.

For more information on defining the scope in response to an incident, see the Control Product section under Response.

Auditing can be a useful verification tool.

Internal or external auditors can act as a fresh set of eyes to review programs, records, and interview employees on proper response procedures. Auditors can also be used to physically examine the facility and equipment for potential FM risks. If using internal auditors, consider rotating auditors periodically or using auditors from a different area, department, or facility, if the company has multiple facilities, to ensure a fresh perspective.

Documentation

A PROGRAM IS ONLY AS GOOD AS ITS DOCUMENTATION.

FM CPPs should be written and accompanying records completed in a timely fashion.

Establishments should follow industry best practices and regulatory requirements, when applicable, for record keeping, document review, and retention.

Documentation should be complete, legible, truthful, robust, and accessible.

2

**FM
CPP**

PREVENTION

2

PART TWO

Prevention

Where possible, a **FM CPP** should have controls in place to prevent or reduce the likelihood of FM.

It is always preferable to prevent **FM**, but it is not always possible to predict and prevent all incidents; therefore, prevention methods are unlikely to be the only type of control used in **FM CPP**.

Establishments should first apply prevention methods where appropriate and then identify any remaining vulnerabilities that may be handled with detection methods.

Supplier Approval Programs

Supplier Approval Programs are generally robust with many components that serve different functions.

One of those functions can be to reduce the likelihood of receiving materials that contain FM through various components, depending on the material. These programs are only effective if consistently applied so that the establishment only ever receives raw materials, ingredients, packaging, chemicals, equipment, etc. from approved suppliers.

Suppliers should provide assurance that they have met all applicable requirements set forth in the establishment's **Supplier Approval Program** prior to materials being received. Assurance can be provided in various ways including, but not limited to:

- letters of guarantee
- affidavits

- audits
- and verification procedures

The bar for assurance has been raised over the years and establishments often require more prescriptive assurance from a supplier than a simple checklist. A quality Supplier Approval Program will include the reevaluation of suppliers on a regular or as needed basis.

This allows for the establishment to communicate issues with the supplier and request corrective actions in response to an incident.

Although this process can be cumbersome, on-going communication that sets high expectations will help an establishment identify the suppliers best suited for its needs.

Those suppliers will understand the value of reviewing internal processes for improvements based on constructive feedback. However, establishments should be thorough in their own internal investigation before determining the **FM** might have come from a raw material as to not damage the trust between establishment and supplier by false reporting. The entire process will only be improved if the true source is identified.

THE SUPPLIER REQUIREMENTS

should be dependent on the material being procured.

An establishment should not expect the same assurances from a live animal supplier and a packaging supplier.

Although the specific methods will vary, establishments will likely want assurance that the supplier has controls in place for **FM**, such as the various prevention and detection methods provided in this document.

Establishments may even consider a risk assessment of suppliers, weighing the risks based on the materials, as well as historical performance of the supplier. Establishments should understand the role of the entire supply chain.

The supplier to the establishment should also consider risks from incoming materials and utilize a Supplier Approval Program where appropriate. Establishments may require suppliers to implement a Supplier Approval Program as a part of their FM CPP and suggest utilizing this document in developing their FM CPP.⁷

⁷ Additional resources include: CFIA's Hazard Identification Reference Database at <https://active.inspection.gc.ca/rdhi-bdrid/english/rdhi-bdrid/introe.aspx?i=1> and USDA's Meat and Poultry Hazards and Controls Guide at <https://www.fsis.usda.gov/guidelines/2018-0005>

The following sections will review aspects of various materials to consider in drafting a **Supplier Approval Program**.

Beyond the context of **Supplier Approval Programs**, additional information about the materials is provided and may be constructive in developing a FM CPP.

LIVE ANIMALS

Foreign material may be present in the live animal at receiving.

The type of foreign material and potential prevention methods are dependent on the species.

CATTLE

- **BUCKSHOT** may be present inadvertently from hunting or the purposeful use for herding, although the use of firearms for herding is not a suggested practice. Slaughter establishments may require suppliers to have a no buckshot policy for herding as part of an approved supplier program.

Processing establishments may require suppliers to have a buckshot program to visually identify signs and remove buckshot when present. Buckshot is extremely difficult to identify through visual inspection and unlikely to be detected through metal or X-ray detection in large cuts, primals, sides, or carcasses (see Detection section).

Metal and X-ray detection is not feasible or reliable for large beef cuts, primals, sides, or carcasses and is therefore very rarely implemented.

Establishments should consider potential seasonality effects on prevalence of buckshot, such as an increase during the fall hunting season.

- **HYPODERMIC NEEDLES** may break during injection and become lodged in the animal's flesh. Needles may also be introduced if administered via dart gun. Over time the needle may migrate into adjoining muscle tissues from the original injection site. Slaughter establishments may require suppliers to have needle control policies.⁸

Processing establishments may require suppliers to have a needle program to detect and remove hypodermic needles when present. However, needles can be difficult to detect with metal or X-ray detection in large cuts, such as bone-in primals, sides, or carcasses (see Detection section).



⁸ For more information see the BQA National Manual at <https://www.bqa.org/resources/manuals>.

- **ORAL DEBRIS.** Physiologically, FM consumed by cattle are funneled to and become trapped in the reticulum.

FM is not typically found throughout the body of the animal because the reticulum collects the FM and prevents ingested FM from moving throughout the system.

Establishments producing tongues or saving meat from the head, tongue, or cheek may consider prevention methods, such as requiring suppliers to prevent animals from accessing debris and ensuring lairage areas are free from debris, or detection methods post slaughter.

SWINE

- **HYPODERMIC NEEDLES** may break during injection and become lodged in the animal's flesh. Over time the needle may migrate into adjoining muscle tissues from the original injection site.

The vast majority of injections are performed in the upper neck area of swine, making the butt the most likely primal to contain needles.

However, due to migration, picnics and loins may occasionally contain a needle. Slaughter establishments may require suppliers to use needleless injection or have needle control policies.⁹

These policies may include a tracking program to identify an animal or lot which may contain a needle. The slaughter establishment would be notified prior to receiving the animal or lot and may choose to implement a program to handle those carcasses separately with additional measures for the identification and removal of the possible needle.

Processing establishments may require suppliers to have a needle program to detect and remove hypodermic needles when present. However, needles can be difficult to detect with metal or X-ray detection in large cuts, such as bone-in butts, sides, or carcasses (see Detection section).

- **ORAL DEBRIS.** Swine rooting behavior allows for the potential introduction of foreign material through ingestion. Establishments producing heads, tongues, tongue base, or saving meat from the head, tongue, or cheek may consider prevention methods, such as requiring suppliers to prevent animals from accessing debris and ensuring lairage areas are free from debris, or detection methods post slaughter.



⁹ For more information see the Pork Quality Assurance Plus® Education Handbook 4.0 at http://www.porkcdn.com/sites/all/files/documents/PQAPlus/V4.0/Forms/PQAv4e_Handbook.pdf

POULTRY

While poultry do not have the same FM vectors as other species based on their physiological makeup and husbandry practices, poultry are known to pick up and eat whatever is on the ground.

This allows for a variety of potential FM that may enter the poultry houses. General good manufacturing practices should be developed to reduce the potential entry of FM at the rearing houses.

Physiologically, FM consumed by poultry are funneled to and become trapped in the gizzard.

FM is not typically found throughout the body of the birds because the gizzard collects the FM and prevents ingested FM from moving throughout the system.



INGREDIENTS

FM may be introduced into product via ingredients.

The type of FM potentially introduced is dependent on the type of ingredient. Ingredients composed of agricultural commodities will likely have different FM potential from that of non-agricultural or synthetic ingredients.

Each ingredient should be evaluated to determine its risk factor.

To aid in assessing risk, evaluate the nature of the ingredient. Risk assessments should start with where and how the ingredient is processed. Establishments should work closely with suppliers to evaluate potential risks.¹⁰

HARVEST METHODS

- **HAND HARVESTED:**
 Products harvested by people.
Risks from people may include hair, jewelry, gloves, etc.
- **MECHANICAL HARVEST:**
 Products harvested by machinery.
Machines may pick up stones, dirt, metal objects, glass, plastic, etc.

PROCESSING METHODS

- **SUN DRIED:**
 Many spices and herbs are processed by drying them outside and are subject to potential environmental contaminants without an opportunity for any wet processing prior to drying.
These may be considered a higher risk ingredient, but the entire process should be evaluated.
- **MECHANICALLY DRIED (DEHYDRATED):**
 Products undergo a dry preparation step followed by wet preparation step then dried.
Drying process occurs with machinery so this may be a vector for FM.
- **FRESH FRUITS AND VEGETABLES:**
 Products typically undergo a dry preparation step followed by a wet preparation step which helps reduce FM.

Some ingredients may clump together or contain multiple sized particles and some are liquid. The key is to ensure that the supplier has procedures in place to isolate the desired product and the means to separate the undesirable from the finished product. Establishments may require an ingredient supplier to implement an FM prevention program, including the use of screens, magnets, metal detectors, optical sorters, gravity tables, de-stoners, etc., to reduce FM potential. Establishments may determine an internal control is needed as well, such as a screen or X-ray. Employee training is also important to ensure that ingredients are handled in a manner where their packaging materials do not become an FM. See the Training and Detection sections for possible controls.

¹⁰ For more information see the [Risk Assessment Section](#).



Some examples of potential ingredient concerns include but are not limited to:

- Debris in ice or water;
- Rocks, stems, pits, or other debris in agricultural ingredients, such as spices, onions, olives, or jalapenos; or
- Packaging components, see Packaging section.

Note: Generally, as the product and its processing move from a hands-on approach to mechanical systems, the risks also transition from human related (*i.e.* jewelry and hair) to equipment related.

PACKAGING

Packaging materials vary across the industry and may include:

- | | | |
|-----------|----------------|-----------|
| • boxes | • stretch wrap | • string |
| • cartons | • liners | • clips |
| • film | • caps | • inserts |
| • trays | • labels | |
| • bags | • nets | |

Each type of packaging material presents unique characteristics to consider for FM and should be properly evaluated.

Establishments should review packaging material specifications prior to purchase to ensure the materials are fit for purpose and verify materials meet specification upon receipt.

Packaging from raw materials, ingredients, chemicals, and/or work-in-progress (WIP) products, including rework, can contribute to incidents by introducing **FM** or becoming **FM** through damage or misuse.

Once the packaging material has been approved, ensure that employees are trained to open packaging in a manner that will not create additional FM. See training section.

- Packaging should be inspected upon receipt and when opening for use for signs of damage or extraneous materials.
- Liners, bags, and other similar products should be tested upon receipt to ensure the thickness is according to specifications. Inconsistent or thin packaging materials may be more prone to damage.
- Colored packaging materials, such as a blue liner, may be preferred for some applications to enhance detectability.



- Product packaging materials should be stored properly, especially while in use during production. Materials should not be stored about open product zones, where feasible.
- Packaging materials from raw materials, ingredients, chemicals, and product packaging should be removed, accounted for, and stored for reuse or disposed of properly, out of open product zones.
- Work with suppliers to eliminate caps, tabs, ties, or other small pieces from packaging material, when feasible.
- Screens may be used when dumping to prevent packaging materials from falling into product.
- Frozen product should be properly tempered to avoid tears in the liner that may have frozen into crevices.
- Liners should be inspected after product is removed to ensure there are no holes or tears.
- Papers used in production or finished product should be removed entirely prior to rework.
- Re-use bins should be inspected prior to filling for debris and regularly for damage.
- Pallet inspections should be performed based on risk. Potential inspection points might be upon receipt and immediately before inverting.

EQUIPMENT

Equipment is generally one of the primary FM contamination sources in an establishment.

Evaluating the equipment from a maintenance as well as food safety perspective, is critical in preventing FM from equipment.

NEW EQUIPMENT:

Ideally, both maintenance and food safety should be involved when selecting new pieces of equipment. New pieces of equipment may be “new” to the company but truly are used or refurbished. In any case, it is important to consider the following:

- User manual should be reviewed for the make and model of equipment being considered and include:
 - + A schematic, which should be reviewed, preferably before purchase, by relevant parties to understand the design and ensure it is appropriate for the process.
 - + Cleaning recommendations to ensure cleaning practices and chemicals don't contribute to equipment degradation thereby resulting in FM contamination. Microbial interventions may also contribute to degradation and should be discussed with the manufacturer or supplier.
 - + A recommended schedule for preventive maintenance (PM), which includes how often certain parts should be replaced. The establishment may set an alternate frequency dependent on historical data once the equipment is in use.
 - + Any processing conditions that the equipment is not suitable for, *i.e.* temperatures below freezing, wet processes, etc. The manufacturer or supplier should understand the intended use of the equipment and processing environment.



- Review or compile a parts list of removable parts, note their detectability, and determine how the parts will be controlled.
- Verification that the equipment materials are indeed made from material indicated on the specifications and in plant verification that detectable materials are, in fact, detectable in the establishment's process.
- **Note:** Not all metals are easily detected using metal detection. Plastics and other non-metal materials may be impregnated with metal to allow for metal detection. See the Detection section for more information on metal detection and other potential detection methods.
- It may not be feasible or appropriate to utilize only detectable materials. Establishments should perform a risk assessment on equipment or parts that are made of undetectable materials and implement controls as needed.
- Discuss design concerns with the equipment manufacturer. Oftentimes they are willing to design equipment based on the company's feedback and specifications they require. Equipment should be designed in accordance with the Food Safety Equipment Design Principles (FSEDP).¹¹ The FSEDP may be helpful in identifying any potential areas of concern, such as metal to metal or metal to plastic friction points, bolts and nuts above product zones, or labels. Relevant personnel should be familiar with the FSEDP.
- If the "new" equipment is actually refurbished, additional care should be given: looking for damage and ensuring it was restored properly.
- Identify and eliminate where possible any points where product or ingredients can build up. Excessive buildup can damage equipment, potentially creating FM.
- Evaluate the presence of zip ties, wire ties, electrical tape, etc. on new equipment and remove or, if necessary, replace with detectable versions.

EXISTING EQUIPMENT:

Many of the considerations for new equipment may apply to existing equipment, especially if those considerations were not accounted for prior to installing existing equipment. However, existing equipment may require additional considerations:

- PM should be performed as scheduled, with the schedule adjusted in response to historical data or incidents as needed. PM should be documented and the records reviewed regularly. Any damage, missing parts, or abnormal conditions should be reported and investigated accordingly.
- Equipment should be inspected on a regular basis for signs of wear and tear. For example, white belting may yellow over time, which can be a sign of age and weakening. When possible, equipment and parts should be replaced when worn, prior to damage that may cause a FM incident.

¹¹ The Food Safety Equipment Design Principles can be found at <https://www.meatinstitute.org/ht/d/sp/i/192471/pid/192471>

PERSONAL PROTECTIVE EQUIPMENT (PPE) & TOOLS

Items used to protect employees or help them complete various tasks, may also turn into FM.

It can be a balance of ensuring that employees have what they need to perform their duties and preventing unnecessary FM events.

Items such as hair nets, gloves, aprons, and other garments and PPE can potentially become FM if not managed properly.

The same holds true for employee tools such as knives, box cutters, pens, clipboards, screw drivers, stopwatches, etc. and while this is not an exhaustive list, any type of tool or item used by the employee runs the risk of becoming FM.

- **PPE:** Limit the amount of PPE taken at a time. Ensure that single use PPE is immediately disposed of in trash receptacles after use and other PPE is accounted for and stored properly when not in use.
 - + Companies can monitor visually with a hall monitor to ensure the amount of PPE that is taken is appropriate and used PPE is properly disposed of.
 - + Another option is to assign a certain number of PPE for the day and instruct employees to manage their own PPE and notify if they need more in case one is damaged prior to use. Employees should also be instructed to notify if they are missing any PPE from their allotment.
 - + RFID tagging could be utilized for high risk items, *i.e.* clear plastic safety glasses or face shield that are not easily detected.
 - + Utilize PPE designed to minimize FM risk or support FM prevention. For example, glasses and ear protection that attach to helmets; tear resistant gloves; and other durable PPE.
 - + Upon receiving, verify the thickness of gloves, aprons, sleeves, or similar items. Flexible plastics and nitriles used for these should be sufficiently thick to reduce likelihood of tearing. Thickness should be included in the specifications provided by the supplier.
 - + Utilize brightly colored PPE that contrasts with products.
- **TOOLS:** Account for tools as often as necessary and possible. The more frequently an establishment accounts for tools and other items, the faster corrective actions can be implemented and the smaller the scope of implicated product. This can lead to more confidence in the process.



- **BOTH:** Implement a reporting system for damaged or missing PPE and tools. Employees should be trained on the proper reporting procedure, including who to report to. Employees should be instructed to stop using PPE or tools upon noticing damage, to report damage immediately, and to save damaged items for assessment.
 - + Provide designated storage areas away from product zones for PPE and tools when not in use, *i.e.* during breaks.
 - + Some PPE and tools may be designed with metal detectable materials. However, it is important to understand what part(s) are made of these materials and verify the materials are detectable with the specific detection equipment in place. For example, metal detectable ear plugs may have metal embedded in the plugs, but not the string that holds the two plugs together. Detectable PPE can be useful, but should not be relied on as a replacement for proper management practices.
 - + Consider specifically accounting for PPE and tools before and/or after specific potentially higher risk activities, such as rework.
 - + Consider a check-out/check-in process to verify PPE and tools are accounted for.
 - + Tracking numbers or IDs may be assigned and permanently applied to PPE and tools through marking or etching.

CHEMICALS

While FM is not typically introduced through the chemicals themselves, the interaction between chemicals and equipment, may lead to equipment degradation, causing possible FM introduction if chemicals are not mixed properly or if the chemical being used is inappropriate for that piece of equipment.

Check with the equipment and/or chemical manufacturer to ensure that chemicals being used will not cause equipment degradation. Chemical packaging can also introduce FM, see Packaging section.



Employee Good Manufacturing Practices (GMPs)

Establishing robust GMPs can significantly reduce the risk of FM potential by setting parameters, when those parameters are consistently followed.

Although GMPs cover a wider variety of practices, in general, they usually include a combination of the following requirements if an employee is entering the production room. Visitors, including contractors, should also be made aware of GMPs:

- Hair net
- No false nails, and short unpolished fingernails
- Clean smock with no pockets above the waist
- No jewelry, including visible piercings, other than a plain wedding band (no stones) and a medical alert bracelet or necklace, when needed
- No watches
- No food, drink, or chewing gum

This is not an exhaustive list, and the establishment's GMPs can be as specific or as general as needed depending on the risk level posed by the process. Unnecessary items should be prohibited in the production room. Items that are essential to processing and maintaining sanitary conditions should be managed.



Glass and Brittle Plastic Programs

Although best practice is to avoid using any glass, ceramics, or brittle plastics in processing areas, it is rarely possible to eliminate all of these components.

Therefore, many companies elect to implement a glass and brittle plastic program, which may include ceramics if applicable. Along with a policy to limit the use of these materials as much as possible, these programs typically have two other fundamental elements:

REGISTER

This is usually a log or map that identifies each component of the processing area and equipment that uses these materials, such as overhead lights, control panel cases, fire extinguisher gauges, etc.

Companies can elect to monitor the integrity of these materials based on historical data and the risk level they pose to product. For example, glass that is observed directly above exposed product may be inspected daily to ensure that any breakage is identified as soon as possible, whereas glass alongside a wall away from exposed product, may be inspected at a lesser frequency.

As with any inspection activities performed, companies should document the results of these inspections and maintain them on file.

RESPONSE PROTOCOL

In the event of broken glass, ceramics, or brittle plastics it is beneficial to have a written protocol prepared to ensure all the appropriate steps are taken to restore sanitary conditions and limit risk.

These materials pose a unique risk in that they are prone to breakage and tend to create many sharp pieces of various sizes when broken. Actions to consider in a response protocol include, but are not limited to:

- Limiting access to and from the area until sanitary conditions are confirmed as restored;
- Inspecting the bottom of area employee footwear for pieces;
- Cleaning the area with designated tools, i.e. brooms, dust pans, etc., without the use of high-pressure water or air to prevent inadvertent spread of materials; and
- A thorough inspection with flashlights to better identify pieces.

[See Response section for more information.](#)

Processing Steps

RECEIVING PROCESSING STEPS

For all processing steps that utilize equipment or tools, documented checks may be implemented at regular intervals to account for all parts and look for damage.

The frequency will depend on historical data and other considerations, such as the amount of product produced between checks. This amount may be implicated and need to be controlled if a check identifies missing or damaged parts, equipment, or tools.

Frequency is highly variable throughout the industry and within each establishment for different equipment or tools; but some possible frequencies to consider are at the beginning of each shift, mid-shift, end of shift, at production periods, hourly, during break times, weekly, or per batch. More frequent FM verification checks can likely lead to a smaller scope of affected product if a FM event has occurred.

RECEIVING:

Receiving is one of the primary steps where FM can be prevented.

This is the point where products are transferred from supplier to customer; and a robust receiving program can help prevent receiving incorrect, damaged, mislabeled, or defective products or materials, before entering the production stream. While the supplier approval program previously mentioned lays the groundwork for product requirements, the receiving step is where some of those requirements will be verified. Receiving activities may include:

- Verifying product name and material match.
- Inspecting product container integrity. Receivers should check for damaged boxes, containers, pallets, and whether pallets are puncturing boxes.
- Verifying product meets specifications. One potential verification option is utilizing a detection method, however detection at receiving may not be feasible or appropriate for the process. See the Detection section for more information.



DUMPING:

Foreign material may be inadvertently introduced when transferring products, raw materials, or ingredients during dumping.

Foreign material may include wood, plastic, or debris from pallets; packaging materials, such as liners or caps; or debris from the dumping mechanism, employee, or tools, such as a shovel.

- Screens or sifters may be used when introducing non-meat ingredients to prevent foreign material introduction.
- Pallets may be wrapped in plastic or pallet covers to prevent debris from falling into product.
- Slip sheets may be used to prevent potential FM from pallets.
- Consider the use of composite pallets, which are typically less likely to break or splinter.
- Packaging may be inspected before and/or after dumping to ensure there are no loose or missing pieces. Some packaging elements to consider: caps, tabs, liners, labels, ties, clips, dividers, or other packaging. For example, cap, lids, or valves for liquid containers.
- Colored packaging materials and/or pallet wrap may be preferred for some applications to enhance detectability.
- Reusable bins may be inspected on a regular basis to assess wear and tear and identify bins that need replaced prior to breaking.
- If possible, two phase dumpers are recommended. This equipment, also known as breakaway or two stage dumpers, separate the bin or combo from the pallet to reduce the likelihood of debris entering the product stream.
- When deboxing, account for any staples, straps, or other packaging materials. Consider whether wax lined boxes might be preferable to plastic liners in some applications.
- When deboxing frozen products, employ a multi-step inspection process to ensure materials are not embedded within the frozen product.

Fig. 2.1
 Photos of a Mepaco®
 Dumper System
<https://www.mepaco.net/material-handling/dumpers/dumper-equipment-options#683106-overview>



FABRICATION:

For the purposes of this manual, fabrication will include:

- cutting
- skinning
- and any other processing method that includes the use of a knife, blade, or saw, whether manual or automated.
- sawing
- shaving

- Knives, blades, and saw should be:
 - + reconciled for tool accountability. Ideally this should be done for each shift to limit the scope of potentially affected product to its respective shift if a tool is unaccounted for.
 - + replaced on a routine basis in accordance with manufacturer recommendations with consideration for historical trends. For example, if the manufacturer recommends replacement every six months, but the blade historically shows wear or break by month five, replacement every four months may be more appropriate.
 - + fit for purpose. Certain sizes or shapes of knives may not be suitable for certain task and increase the risk of damage if not used appropriately.
 - + inspected on a routine basis for wear or damage. The inspections should be recorded for reference to identify the time period of production involved during an investigation.
 - + sharpened regularly according to best practices and manufacturer recommendations, if applicable. Sharp tools are easier to work with and typically break less often because less pressure is needed.
- Knives may be properly “tipped” to round off the tip of the knife to prevent breakage, according to company procedure.

COMMINUTING:

For the purposes of this manual comminuting includes grinding, shredding, dicing¹², emulsifying, Advanced Meat Recovery, and other similar methods.

FM introduced at these steps may become comminuted as well and dispersed throughout the product, widening the scope of an incident. The potential for FM to be reduced in size can impact the detectability.

- Some equipment may have or can be adapted to include a bone collector. These should be utilized, if possible, and monitored regularly.
- Equipment should be monitored on a regular basis for signs of damage or debris.
- The use of detection systems before comminuting can be useful to prevent debris from entering the system.

¹² Diced products are not necessarily considered comminuted in regards to assessing microbial risk. FSIS guidance delineates diced products less than ¾” in all dimensions as comminuted.

MECHANICAL TENDERIZATION:

Tenderization equipment is somewhat unique in that it penetrates the surface of the product without dividing the product, like comminuting or knife cutting does.

This poses the risk for needles or blades to become lodged in the product, not visible from the surface of the product.

- Needles or blades should be inspected, at a minimum, each shift. Ensure that the needles or blades are correctly installed to reduce breakage.
- Bent needles should be replaced when identified.
- Be aware of the total number of blades or needles that should be installed in the machine, or at least how many the company decides to install per company standard operating procedure. Account for needles or blades at some frequency, preferably daily. Daily monitoring can help in reducing the scope of affected product in the event that one goes missing.



INJECTION AND TUMBLING:

FM Risk from injection is similar to mechanical tenderization; however, injection and vacuum tumbling have the unique element of forcing or drawing solution into the product.

If the FM is small, it could pass through the injection system and enter the product with the solution or be drawn inside the product during vacuum tumbling.

- Any type of injection process should be evaluated and an accountability program can help minimize the scope of affected product if a needle goes missing or is damaged. Injection equipment can often incorporate an alert system to help identify when a needle might be missing or damaged.
- Tumbling is not typically a vector for FM but should still be evaluated for risk, because any FM introduced into the tumbler may be spread throughout the entire batch, increasing scope.
- Product and ingredients should be handled carefully prior to injection or tumbling, including the solution.
- Brine or other solution systems should utilize filters and all parts should be inspected on a regular basis for damage. Recirculation systems must be taken into consideration.

REWORK:

One of the riskiest steps in many processes is rework, predominately because product is exposed multiple times to the processing environment, often with more obstacles to consider.

Products from different time periods may be mixed together, increasing the overall window to analyze during an investigation. There are several aspects to consider to reduce the likelihood of FM during rework:

- If comingling rework with current production, limit the scope as much as possible.
- Avoid introducing reworked product multiple times, *i.e.* product has been reworked into production and a portion of the resulting comingled product needs reworked. If this product is then comingled into current production, the resulting product represents three different time periods of production in one.
- Consider creating a clean break procedure on rework, such as discarding product if not reworked within a predetermined time period.
- Put additional controls in place when reworking: visual inspection, additional employees, offline detection system, etc.

- Account for PPE and tools before and/or after reworking.
- Rework procedures may differ depending on the reason for rework. If product is reworked solely for quality reasons the process will likely look different than product being reworked to identify and remove potential FM. See Detection section for more information to evaluate potential methods.

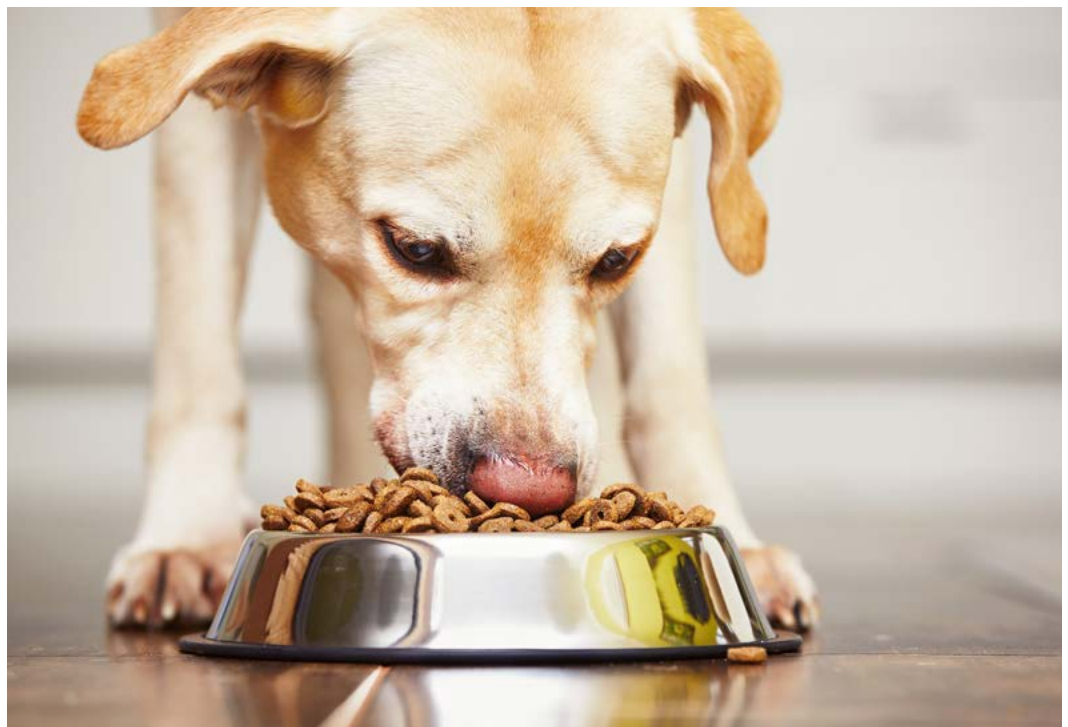
Assess the risk level associated with reworking returned product.

INEDIBLE OR RENDERING:

Depending on the intended use of inedible or rendered product, it is important to keep in mind that FM should likely not be present in these materials either.

Some of these materials may go into animal feed or pharmaceutical products and may have specifications that prohibit FM.¹³

The suggestions in this document may apply to these products as well.



¹³ **REGULATORY REQUIREMENTS:** If destined for animal feed, the Preventive Controls for Animal Food regulations under the Food Safety Modernization Act apply. 21 CFR 507

Sanitation

SANITATION

The transition from the end of production to the handoff to sanitation and the sanitation process itself sometimes can lead to misplaced parts and possibly the **inadvertent introduction of FM** if not managed effectively.

Also utilizing contract sanitation companies may impact the complexity of the production/sanitation handoff. It is important to first understand the equipment and the associated parts. Refer to equipment section of the guidance for details.

- Once the equipment is well understood, an equipment checklist should be developed to ensure all gaskets, bolts, belts, pins and whatever else is removed during sanitation or teardown is accounted for.
- Sensitive equipment elements should be designed with protection in mind and must be handled with care to prevent damage; without the use of temporary protective coverings, such as tying a plastic bag around a control panel.
- Hoses, ladders, brushes, scrub pads, towels, squeegees, belt props, and other cleaning tools should be maintained in good condition and accounted for prior to the start of production.
- PPE and tools should be controlled and reconciled prior to the start of production. See section on PPE and tools.



Maintenance

Maintenance employees are one of the experts on the equipment used in a company's processing facility and are an integral part of FM prevention.

When maintenance is working on or above equipment, tool accountability is critical.

- Tools, cart, and lifts used in the production environment should be kept clean and in good condition to prevent transfer of FM from maintenance workshops and other areas.
- If a part(s) must be replaced, the replaced part(s) should be accounted for so it is not left out on the production floor. This ensures the replaced part(s) is not used in some other manner and prevents it from becoming FM. The replaced part(s) should be inspected for damage, which may indicate a potential incident. Written programs and documented reconciliations are recommended.
- Routine preventive maintenance (PM) can be a useful tool to identify parts and pieces of equipment that are becoming loose or damaged and replace them before they become potential sources of FM. Written programs and documentation are recommended.

Parts Allocation

New and replacement parts should be properly managed and accounted for.

Personnel responsible for replacement should not be allowed free access to parts such as gaskets, belt pins, rubber seals, etc.

- Some establishments have designated personnel to manage and document parts allocation.
- It may be beneficial to require the old part be returned prior to providing the new.
- The number of parts provided could be limited.
- Parts should be verified to ensure they are fit for the equipment or use, according to manufacturer recommendations. Use of the incorrect part could lead to equipment damage that may lead to an incident.
- Conduct a post maintenance inspection prior to release of a work area back to production.

Employee Training

Training is critical for every step in the production process.

Without training, almost any substance within the facility can become a potential FM.

Training should be conducted prior to starting an initial or new position. Refresher training should be conducted on an ongoing basis and as needed.

Training should be specific to the task being performed and in general should be comprehensive to ensure food safety. For the purposes of this document, training should include procedures with FM prevention in mind.

Examples of training opportunities:

- Ingredient opening procedure to ensure bags are opened in a sanitary manner. Any zip ties, or caps that may not have been designed out of product packaging are accounted for. If the formulation calls for 3 bags of ingredients and each bag has a tie, before moving to the next step in formulation, an employee must account for all three ties. If the employee cannot account for all 3 ties, further investigation is needed and product may be placed on hold pending further investigation.
- Design procedures and train employees such that any packaging that disconnects from the original container is disposed of immediately. For example, opening up a spice bag typically requires cutting the top of the bag and removing the top portion of the outer layer of the bag. Train employees to immediately place this in the trash to prevent the likelihood of it ending up in the spice blend.
- Design the sanitation program to include clearly identified trash receptacles, inedible containers and any other specific containment practices that are performed and explain the purpose behind it.
- A supportive company culture should be conveyed to new and existing employees and implemented on all shifts. If they “see something,” they “say something”.
- New or transferred employees should be shown examples of potential FM or things to look for in equipment that may signify an incident. All employees should review this information on an ongoing basis. Following an incident, learnings should be shared with area employees.

Training should also include a method of verification to ensure that training is effective. For example, conducting mock events can give the company a realistic sense of how a FM event would be handled.



Visitors

VISITORS

People visiting the facility may not be aware of the typical processing environment and the GMPs being implemented.

It is up to the establishment to enforce strict GMPs for visitors to prevent any type of FM introduction from a person that may not be familiar with food production.

Establishments may elect to incorporate the visitor policy into the GMPs or have a standalone visitor policy.

In either case, the policy should include advanced notification to the visitor, if possible, to ensure they are wearing the appropriate footwear, and simply preparing them for the visit. Jewelry allowances should be kept to a minimum. Companies should evaluate visitor risk based on how close the visitor will be to exposed product and what they will be doing in the facility.

Examples of possible scenarios where visitor risk is evaluated:

- Visitors are not allowed on the production floor and only are allowed to view production from windows. This poses the least amount of risk to product.
- Visitors are allowed on the production floor and must follow all GMPs. In addition, they must stand away from open hoppers. This is the scenario that most likely mirrors what the majority of facilities allow. With this type of visitor interaction, it is important that the GMPs prevent any type of objects allowed in smock pockets.
- Visitors are allowed to interact with the product. This is the highest risk and should only be allowed in certain cases. These visitors might be consultants who have been hired to help with product development. In any case, the tools or equipment that visitors are bringing with them should be accounted for prior to them leaving the floor and detectable, if possible.
- Some third-party contractors visit the establishment on a routine basis and may be deemed as low risk because of additional training administered and longstanding contracts with requirements that protect the establishment. Examples may include:

- Pest Control
- Sanitation
- Scale service
- Water Filtration
- Chemical service

A general recommendation is to have an establishment employee accompany the visitor while on the production floor, when deemed necessary. This can help with ensuring visitors adhere to GMPs and stay in designated, allowable areas.

3



DETECTION

3

PART THREE

Detection

Detection can play a role in a FM CPP for monitoring or verification of preventive measures or as a control step.

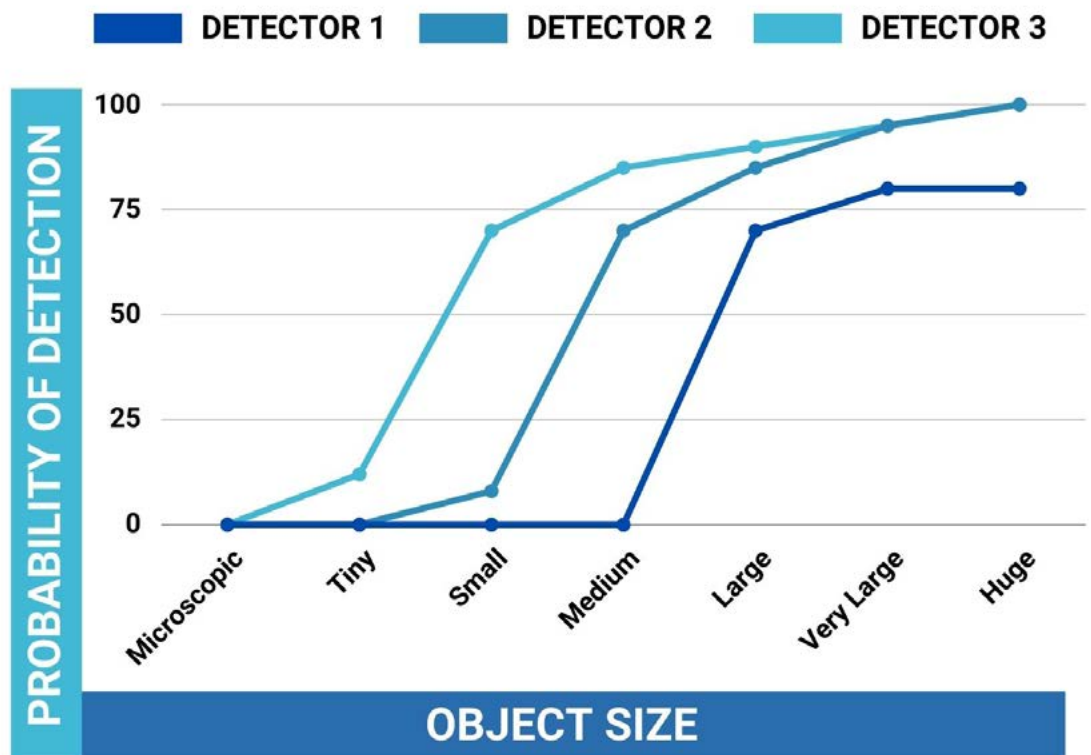
Each detection method has strengths and limitations that should be considered.

Not all FM can be detected by every detection method in every product.

The establishment should work closely with the detection machine supplier to ensure the detection technology is appropriate for the target **FM** and process under standard operating conditions and is or will be used as designed.

Detection capability is predominantly influenced by resolution (the smallest object that can be detected), noise (how close is the detection signal to the background), and speed, although specific methods may have other factors to consider. Most detection methods have increased detection success as FM size increases.

Fig. 3.1
Examples of detection curves for different detectors. Probability of detection of an object increases as size of the object increases. Noise, object type, presentation configuration, background information, system configuration and environment all affect detection success.



No detection method is perfect and all possess the potential for false predictions, to some degree.

It is commonly understood that false positives, where rejected products does not contain FM, and false negatives, where FM goes undetected, may occur in any system.

A Confusion Matrix can aid in understanding and evaluating different methods and sensitivity settings:

		ACTUAL (True Condition)	
		POSITIVE	NEGATIVE
PREDICTED (Measured Condition)	Predicted Positive	True Positive (TP)	False Positive (FP)
	Predicted Negative	False Negative (FN)	True Negative (TN)
		P = TP + FN	P = TP + FN

Fig. 3.2
Confusion Matrix

The key is to **minimize false predictions**, whether positive or negative, to the extent possible, while maintaining a reasonable balance of detection. A high false positive rate can waste a significant amount of product and resources through verification; whereas, a high false negative rate can put product at risk. The false prediction rates of a detection method should be well understood before implementation.

The ability of any detection method to detect FM can typically be enhanced to reduce false negatives, often referred to as **increasing sensitivity**.

However, in many detection methods, increased sensitivity can result in a higher false positive rate. Speed can play a role in this relationship as well. It is generally only feasible to detect large FM in fast moving systems, where slower moving systems may be able to detect smaller FM. However, every system is unique and must be evaluated on a case by case basis. Establishments should consider the balance of sensitivity when determining which detection method to implement, if any.

OVERVIEW OF **Common Detection Methods**

The success of **detectability** is dependent on numerous factors specific to each method.

These factors are highlighted throughout the section.

Detection Only

The following methods are for detection only and must be paired with a reject mechanism to remove detected materials. See section on reject mechanisms.

METAL DETECTORS

FUNCTIONALITY

Metal detectors transmit an electromagnetic field from one or more transmission coils.

Metal objects within the electromagnetic field created by the detector become energized and retransmit an electromagnetic field of their own.

The detector receives the retransmission from the metal object through a receiver coil allowing the detector to recognize the object's presence.

This is why metal detectors can only detect metal, hence the name. Other objects such as glass or plastic are not effective conductors of electromagnetic fields. When applicable, establishments should verify the metal detector is capable of detecting the targeted FM. For example, if the target FM is metal belt links, verify the specific link in use is detectable.

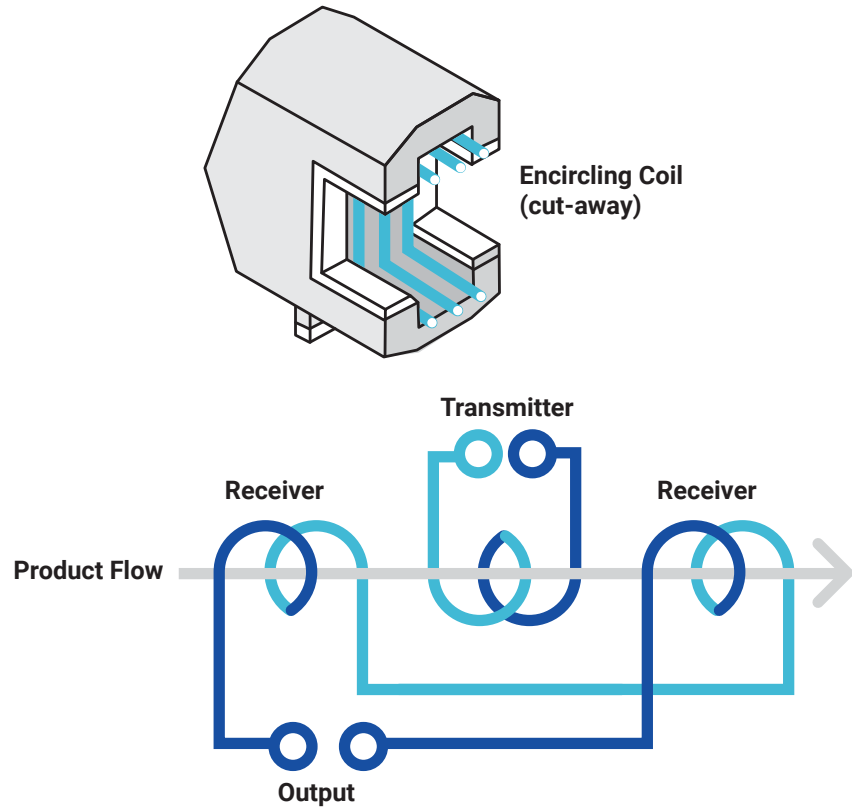


Fig. 3.3
Metal Detector

Functionality Factors

- Type of metal:** Metals with high electrical conductivity like aluminum or brass retransmit a stronger electromagnetic field and are easier to detect. Unfortunately, stainless steel, one of the most common metals used in meat and poultry processing environments, because of its anti-corrosive properties, has low electrical conductivity and can be harder to detect. This is why different sizes of standards are often used for calibration. For example, an establishment may use a 3.0 mm ferrous standard, a 4.0 mm non-ferrous standard, and a 7.0 mm stainless steel standard.

Metal Type	Magnetic Permeability	Electrical Conductivity	Ease of Detection
Ferrous (Chrome Steel)	Magnetic	Good	Easily ¹
Non-Ferrous (Brass, lead, Copper)	Non-Magnetic	Generally Good or Excellent	Relatively Easily ²
Stainless Steel (Various Grades)	Usually Non-Magnetic	Poor	Relatively Difficult

- Shape and orientation of the FM:** The detectability can vary depending on how the FM is oriented when it passes through the metal detector. For example, if a linear metal wire or hypodermic needle passes through parallel to the conveyor and perpendicular to the aperture, it may not be detected. If the same wire were balled up or the needle passed through parallel to the aperture it might be detected.

Orientation becomes a problem when the width of the smallest dimension is less than the standard.

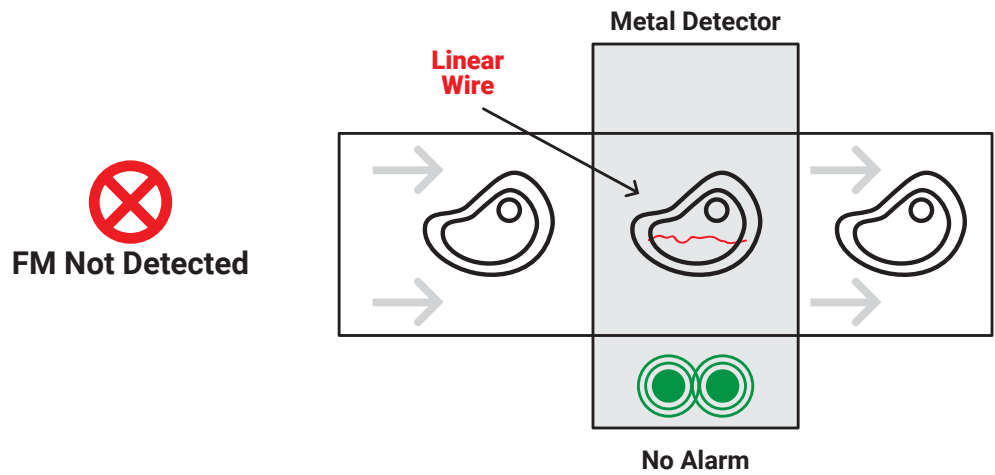
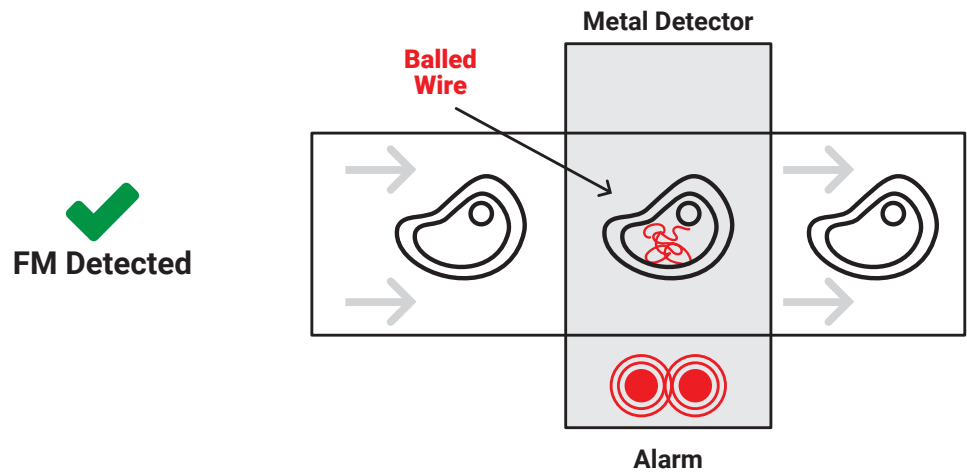


Fig. 3.4

Shape and orientation in metal detector



FM Detected

Alarm

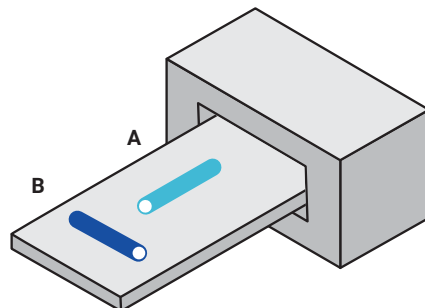


Fig. 3.5

Shape and orientation in metal detector

	A	B
Ferrous (Chrome Steel)	Easy	Difficult
Non-Ferrous (Brass, lead, Copper)	Difficult	Easy
Stainless Steel (Various Grades)	Difficult	Easy

APPLICATION

Metal detectors should be fit for purpose, optimizing detectability for the specific process, and are not mutually interchangeable.

A detector that is no longer needed in one area might be able to be used in another area, but only if the design is also appropriate for the new area and the detector is validated.

REMINDER, it is recommended to work with the supplier to ensure the equipment is appropriate for the process.

Application Factors

- **Aperture:** The space in the center of the detector where product passes through and the transmission coil projects an electromagnetic field. The sensitivity of the detector is measured at the geometric center of the aperture, which is the least sensitive point.

Generally speaking, the smaller the aperture, the more sensitive the detector. To maximize sensitivity, aperture size should be the smallest possible while still allowing product to flow freely without contacting the detector. However, in some applications a larger aperture with the product properly centered could reduce product interference noise providing better detect results.

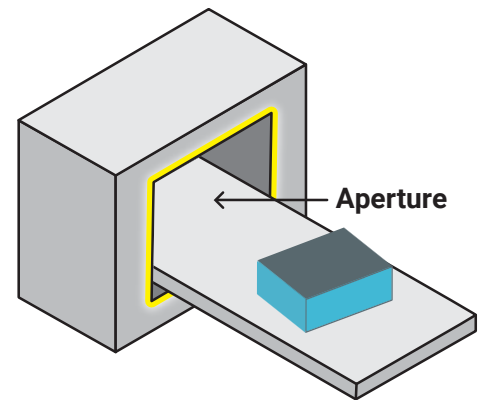


Fig. 3.6
Aperture

- **Product size, density, variation, and orientation:** Large diameter and/or higher density products are more difficult to metal detect. The more variation introduced to the detector, the more the detector has to account for in what is often referred to as background noise.

For example, it is more difficult to detect FM in a large, bone-in primal than a comminuted product. Products piled up on top of each other or in contact with the metal detector will deter detection. Products with high salt content can also prove problematic, because salt is made up of a metal, either sodium or potassium, and a chloride.

Other factors include moisture and acidity. Establishments should work with the manufacturer to determine the best system for the specific application.

- **Process speed:** The speed of the conveyor or other transfer mechanism is crucial. Most metal detectors used in meat and poultry processes utilize a balanced coil system, meaning there are two receiver coils that are designed to pick up the disturbance from the FM as product enters and leaves the aperture to determine the difference, like a seesaw.

If product moves too quickly, the imbalance will not be detected. On the other hand, no imbalance can be detected if the product is stationary. The conveyor must be moving so product flows through the aperture to accurately detect any imbalance caused by FM.

Many new systems have the capability to automatically match process speed utilizing speed sensors, but legacy systems will likely not have this feature.

OPERATION

When using a metal detector, it is critical to understand the functionality and limitations.

For optimum performance, sensitivity settings should be adjusted for each product or product type.

Operation Factors

- **Product temperature:** It is generally easier to detect FM in solid frozen products because of reduced background noise. *Uniformity in temperature is key:* if a frozen product begins to thaw on the line or the center is unfrozen, the variance in temperature can impact detectability and is likely to cause a high rate of false rejects.
- **Environmental Location:** Metal detectors can be affected by forklifts, plant vibrations, mechanical movements by surrounding equipment, or even other metal detectors with the same frequency. The detector must be fully isolated from other equipment and installed correctly to avoid these potential interferences.
- **Preventive Maintenance:** Regular PMs and inspections in accordance with manufacturer recommendations are essential to maintaining optimum performance.



CALIBRATION

Although metal detectors are not calibrated in the traditional sense, they can be tuned and balanced by a trained technician upon installation and as needed.

On a regular basis, metal detectors must be verified for the specific product(s) and process used, especially after sensitivity settings have been adjusted.

Verification is typically performed by running standards through the aperture to verify the machine is able to detect that specific size and type of metal, usually ferrous, non-ferrous, and stainless steel.

Standards are usually plastic wands or cards with a piece of metal of a specific type and diameter embedded. Having the metal embedded in a larger piece of plastic helps to prevent the standard from being inadvertently lost or integrated into the product. Standards can also be made from FM the detector is being asked to target.

For example, a processor might create a standard by placing a screw in a plastic case or bag; if the detector is targeting that particular type of screw. Verification should be performed by running the standard with product at normal processing speed. The same standard should be run multiple times in a row with product at various locations in the aperture to verify repeatability, or the machine's ability to detect the same object in succession, and determine any weak spots in the aperture, respectively.

More information on metal detection technology can be requested at <https://www.mt.com/us/en/home/library/know-how/product-inspection/PI-Guides/metal-detection-guide.html>.



X-RAY MACHINES

FUNCTIONALITY

X-ray machines transmit energy in the form of “X-rays” through product from one side.

On the opposing side of the product a detector measures how much energy passed through to determine variances in density. The denser the material, the less energy passes through.

Functionality Factors

- **Density of product and FM:** For X-ray machines to be effective, the FM must be more dense than the product. Generally, if the FM sinks in water it is potentially detectable through an X-ray machine. Wood, paper, and many plastics are not dense enough to distinguish from meat and poultry products and are typically considered non-detectable materials. Higher density materials such as metals and lower density, but still detectable, materials such as glass, calcified bone, stone, ceramic, and cement are typically detectable.

Although aluminum is a metal, it is low density and can be difficult to detect depending on the application. However, it is important to account for the product.

For example, the density of pork bone and glass are very similar, so utilizing an X-ray machine to detect glass in a bone-in pork product will not be effective, while detecting a hypodermic needle is feasible. Also, dense products like large comminuted, formed meat blocks are challenging for the lower density materials, such as glass and bone at smaller sizes.

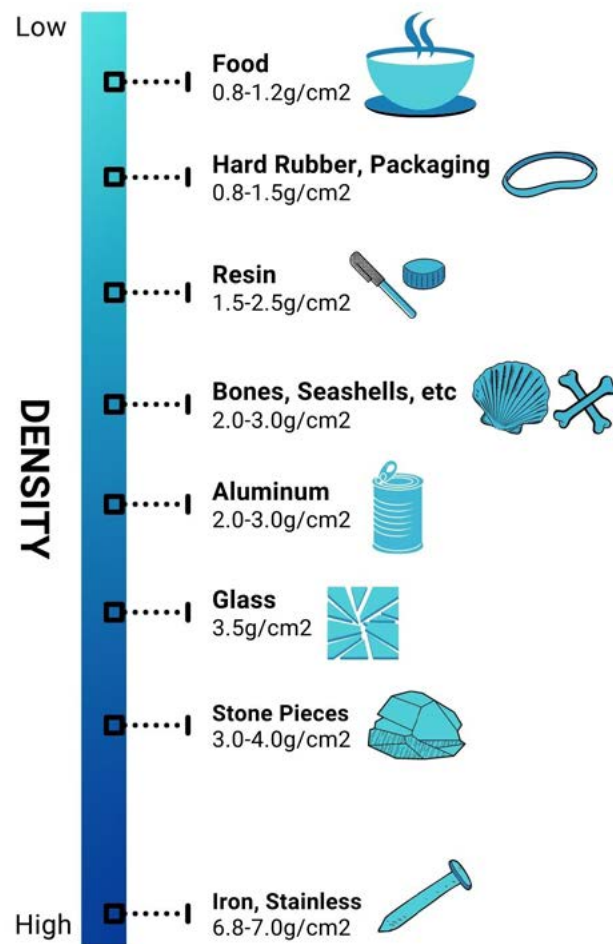


Fig. 3.7
Density Weights

APPLICATION

X-rays are typically more flexible than metal detectors and can be used for a variety of applications. However, the X-ray must be programmed for each different application and the program settings selected when switching between preprogrammed applications.

Application Factors

- Training the X-ray:** Each X-ray must be trained to recognize what normal looks like for that process. Training is done by exposing the X-ray to the normal process speed, product orientation, and all the different products that may be monitored so it can develop a program to recognize deviations. Any normal variation should be accounted for during the training, but increased variation can limit detectability, so it should be as limited as possible.
- Single energy vs. dual energy:** X-ray systems measure the attenuation of energy that transmits through the various inspected food products. There are different wavelengths that can be measured and compared providing digital information about the physical attributes of the product and the contaminants. Single energy only analyzes the high energy wavelengths and is generally effective at detecting metals and detectable lower density materials based on density as it compares to the product itself. Dual energy compares high energy x-ray waves with low energy waves to identify the difference between organic versus inorganic material. Dual energy is recommended in some applications to achieve better lower density detection of materials such as glass, stone, rubber, or bone*. Dual energy can better account for variability in density within the product itself such as in a bag of chicken nuggets or sausage links, up to a certain density level. Dual energy is not universally better than single energy, or vice versa, and it is recommended to discuss the appropriate technology with the supplier based on the targeted FM and the product.

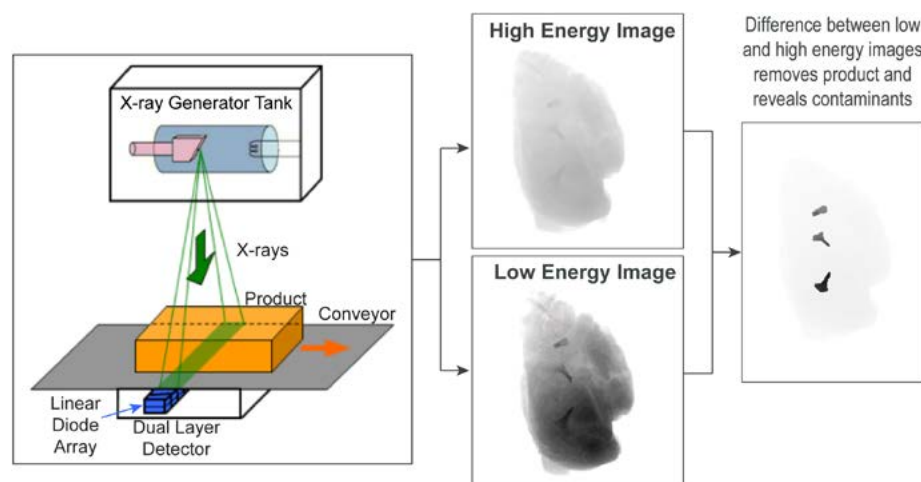
NOTE: Images are the property of Anritsu and inserted as examples only. When appropriate, Erik can ask for copyright release.

What is the Dual Energy System?

Principle of measurement with dual energy sensor system.

The dual energy sensor captures high and low energy images at the same time and identifies differences between the two images to focus on the target foreign object.

Fig. 3.8 Dual Energy System





Solving the issue with X-ray Inspection Systems

1. Detection of low density contaminants.
Make low density contaminants visible in order to spot them.



2. Overcoming an image when a product sits on top of the product
In order to minimize the effect of the layer, nify the contrast shadow of multiple thickness part and single thickness part.



Fig. 3.9
X-ray Inspection
Systems

OPERATION

When using an X-ray, it is critical to keep the machine clean and debris free for optimum performance.

Operation Factors

- **Environmental Location:** Unlike metal detectors, X-rays systems are generally not affected by environmental concerns. However, proper cleaning protocols are recommended to assure the belt is free of any material that could create a variance in density within the image.
- **Preventive Maintenance:** Regular PMs and inspections in accordance with manufacturer recommendations are essential to maintaining optimum performance.

Note: X-ray systems for food inspection are typically classified as cabinet X-ray systems, the most stringent design, providing necessary guarding and interlocking to retain the low energy X-ray within the system itself. Within the USA, systems meet 21 CFR 1020.40 design regulations and within Canada they are to be designed to the Canadian Red Act. The equipment typically needs to be registered with the local state or province. Your X-ray equipment supplier is a valuable resource for more information and education.

CALIBRATION

Training the X-ray is the first step for calibration.

Once training is completed, X-rays can be calibrated similarly to metal detectors, using standards.

Standards are typically run through the X-ray to verify the desired FM can be detected. Wands are rarely used with X-rays, as the wand itself may trigger the X-ray. Typically X-ray standards are thin cards with a piece of metal, glass, or other material embedded. Just as with metal detectors, standards can also be made from FM the detector is being asked to target. For example, a pork processor might create a standard by placing a hypodermic needle in a plastic case or bag; if the X-ray is targeting broken needles in pork butts. Fresh bone may be used to create a standard for bone, but establishments should work with the equipment supplier to find an appropriate standard for bone, if needed.

More information on x-ray detection technology can be requested at <https://www.mt.com/us/en/home/library/know-how/product-inspection/PI-Guides/xray-inspection-guide.html>.

VISION SYSTEMS

FUNCTIONALITY

There are three types of vision systems:

- camera
- multispectral
- hyperspectral

Each uses digital sensors with specialized optics to capture images that computer hardware and software process, analyze, and measure to determine acceptability based on predetermined settings. Vision systems depend on the interaction of light wavelengths with the product. Although most common vision systems use cameras in the visible light range, other wavelength ranges such as ultraviolet (UV), Near Infrared (NIR) or Infrared (IR) can be used to measure components of the product that are not easily detected in the visible range.

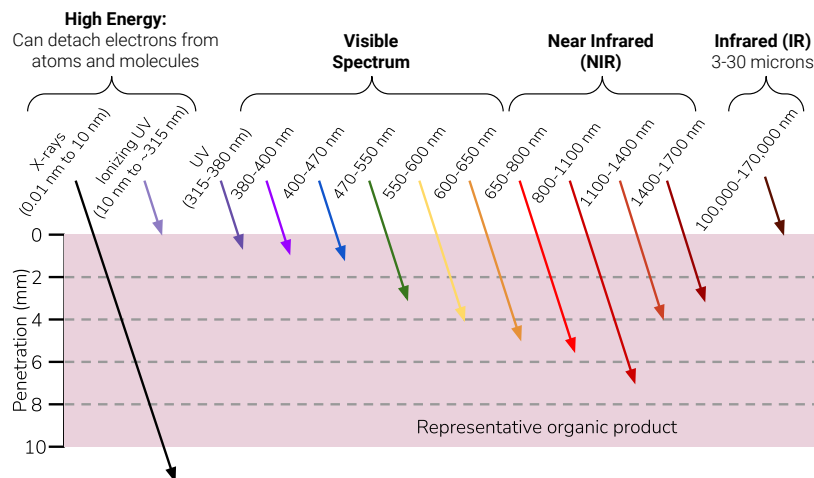


Fig. 3.10
Penetration of light of different wavelengths in a typical product.

Camera:

Standard camera systems typically capture three color bands: red, green and blue. These are the same color bands that the human eye is receptive to, so images produced resemble human vision. Camera systems are the most basic of the three, provide very high speed of detection, and have been used in multiple industries for decades. However, cameras are limited to detecting high contrast items on the product. For example, light colored objects on light colored products will be very difficult to detect.

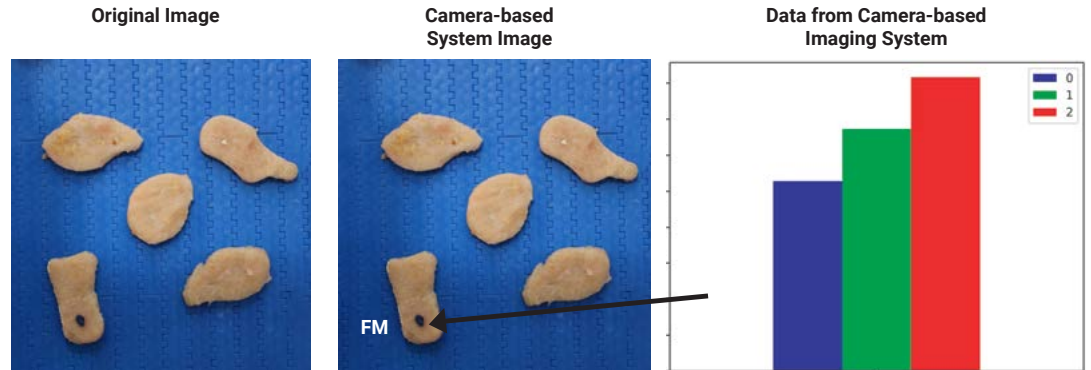


Fig. 3.11
Example of a camera system and the color bands in use.

Multispectral:

Sensors capture 5-30 color bands, sometimes including bands outside the normal range of vision. Bands may be selected to differentiate objects of interest, allowing for the ability to recognize basic chemical composition. For example, detecting a certain type of plastic requires bands of light most likely to be absorbed by that plastic. Multispectral systems are limited by the selection of color bands and are best suited for the detection of very specific chemical compositions. For example, a new plastic with different chemical composition may not be detected by an existing multispectral system.

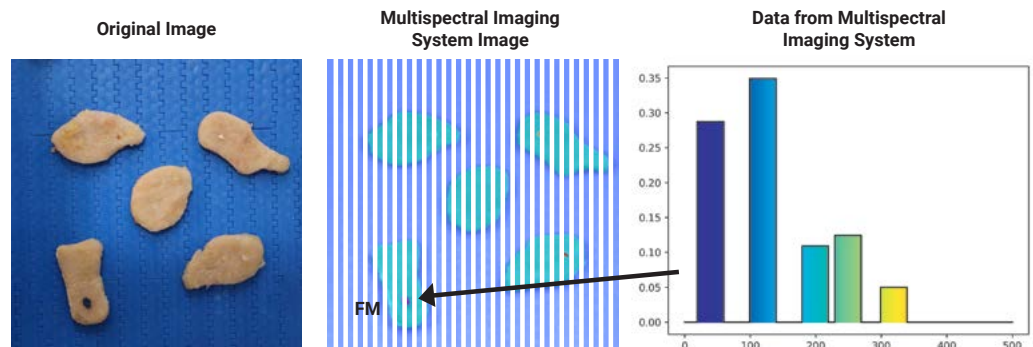
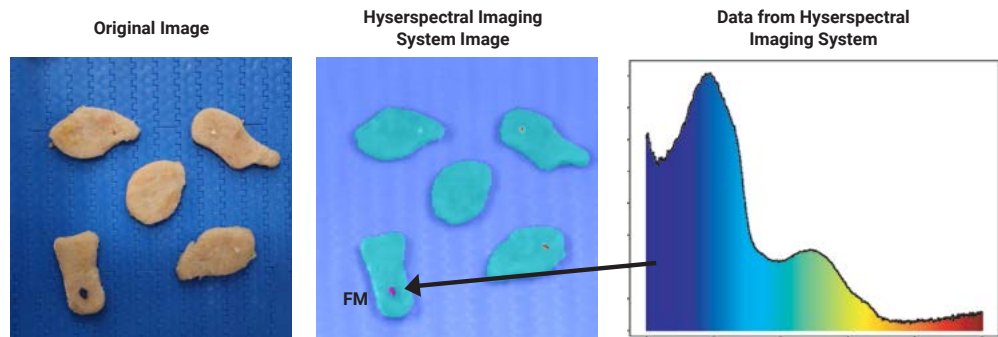


Fig. 3.12
Example of a multispectral system image and the color bands in use.

Hyperspectral:

The most complex systems available; with sensors that capture hundreds to thousands of color bands per pixel, many of which are outside the normal range of vision. The large number of bands allows for the ability to differentiate the chemical composition of each pixel and “learn” new chemical signatures over time. For example, these systems can often differentiate same color plastics by detecting chemical composition differences between samples. Hyperspectral systems are highly flexible in detecting the largest variety of objects, including objects with previously unknown properties. However, these systems are limited by speed, and often the pixel size available; and precise lighting is required. New development in detectors and computing power have made hyperspectral inspection possible for most meat and poultry processing applications at line speed. These systems can evolve to address product specifications, such as measurements, and detect FM in real time, because of the unique ability to learn over time.

Fig. 3.13
Example of a
hyperspectral
system image and
the color bands
in use.



Functionality Factors

- **Resolution:** Though it is related to the pixel size used, resolution is actually a measurement of the smallest particle that can be distinguished by the detector. At least two pixels are necessary to resolve a small object and often that number must be much higher. Generally, resolution does not mean the smallest detectable size of FM. It is a measure used in “perfect” conditions, using best contrast, orientation, and illumination. This measure should be used only as a guidance and quick comparison for very similar systems.
- **Location of FM:** Vision systems can detect objects located at or very close to the surface of the product (within a few millimeters). FM underneath or on the sides of a product typically cannot be detected, unless the vision system has additional imaging heads or product presentation methods. Two-sided imaging can be performed by using a “waterfall” configuration where two detection systems see the product falling between two conveyors, one from each side of the “waterfall”. Other systems offer multiple vision heads and shake or disturb the product so that multiple sides of the product are exposed. Finally, some systems flip product and capture images both pre and post product flip.
- **Type of FM:** Understanding what materials can be detected by a vision system will help determine the appropriate type of system for the process:
 - + **Camera:** detectable objects should have significant contrast or color difference from the product. For example, opaque, dark blue plastic should be relatively easy to detect; however, translucent, light color plastic would be difficult to detect on a light-colored product. Also, uniformity of the product greatly affects detectability. Detecting a small object is easier on a uniform fat layer than on a roughly ground red protein and fat mix.

- + **Multispectral:** Performs much better than camera systems in low contrast situations, especially when the selected color bands correspond to the FM's chemistry. For example, a system tuned to a specific belt material should be able to pick out that material regardless of the color or contrast with the underlying product. Due to the selective color bands in multispectral systems, not all materials will be differentiated from the background material, regardless of their visual appearance. It is best to use multispectral systems for well-defined processes, where all possible FM are well understood and catalogued.
- + **Hyperspectral:** Particularly useful for low contrast detection on complex product surfaces. Due to the ability to see chemical composition instead of just color, these systems can also detect translucent materials and, in some cases, even very thin films. Hyperspectral systems also provide the ability to flag any foreign object that has not been seen before, only based on the fact that its chemistry is sufficiently different from the product. These systems provide the most flexible vision detection where there may be a variety of FM or the FM is an unknown material.

APPLICATION

Unlike x-ray or metal detectors, vision systems tend to collect information from the surface of the product.

Some systems are able to penetrate deeper, but with decreased detection ability for embedded objects. The general advantage of vision systems is to detect objects of any density or composition.

Application Factors

- **Training the System:** All vision systems need to learn what a "typical" product looks like in the various orientation, presentation, moisture, and illumination configurations it may encounter.
 - + **Camera:** Objects that look unnatural, have sharp edges, or very different colors from the "typical" product are flagged. Although artificial intelligence (AI) may be used, traditional image processing methods are still common.
 - + **Multispectral:** Color bands are selected to provide the best differentiation between the product and a possible FM. The system is then uniquely built and algorithms developed to identify objects that are different from the "typical" product.
 - + **Hyperspectral:** The product is analyzed with and without FM so that complex algorithms can be developed to differentiate FM from "typical" product. Hyperspectral systems typically are designed to learn over time, so that new FM are not only detected but identified over time.

OPERATION

Vision systems require light and an unobstructed view of the product to function properly.

Operation Factors

- **Illumination:** There are various illumination methods used, depending on the type of system. Generally, camera systems require the least complex illumination, with components that rarely require replacement. Multispectral systems might use laser illumination, making a robust enclosure necessary to protect the eyesight of area employees. Hyperspectral systems often use stronger, brighter lights that may produce heat over time, requiring proper heat dissipation and the potential for regular lamp replacements.
- **Environment:** An unobstructed view of the product is critical; therefore, dusty or aerosol heavy environments should be avoided. Most vision systems include built-in illumination and shielding so that external lighting conditions do not affect them. All vision systems will require periodic cleaning of optical elements and lights to maintain a clear view for detection.
- **Preventive Maintenance:** Regular PMs and inspections in accordance with manufacturer recommendations are essential to maintaining optimum performance.

CALIBRATION

Vision systems require various levels of calibration to ensure the programming reflects the real-world application and captures quality images. The first two levels are completed by the original equipment manufacturer before the system is delivered to the establishment.



The first ensures linearity, uniformity, and bad pixels are quantified and correction factors are created. Spatial corrections are then applied to correct any distortion to make sure the camera itself does not influence image quality.

Once the vision system is configured with illumination, **spatial mapping** is used to correct for the specific application. Spatial mapping connects the pixels of the sensor to the real world by imaging targets, such as a grid pattern, of a known size and shape. This can correct for perspective distortion, where the angle or perspective of the camera changes the perceived shape of the image. In addition, color vision systems require color-balancing in order to fine-tune the response of each color channel. The quality of the illumination source will affect the degree of color correction that is required.



The final step of vision system verification is at the application level and vary based on the task conducted by the system. Similar to metal detectors and X-rays, standards may be used where a known example of FM is embedded inside a transparent material. Standards can include a range of material types and sizes, again dependent on the FM the system is designed to target.

Reject Mechanisms

Establishments should evaluate which reject mechanism is appropriate for the detection method and process.

This is another aspect where the supplier may be helpful in assessing and recommending a solution.

Once a reject mechanism is chosen, it must be properly set up to work in tandem with the detection method. Process speed, layout, and the detection equipment will determine the implicated zone that must be rejected by the mechanism.

For example, a slow conveyor might have an implicated zone of only a foot or one piece of product, where a faster conveyor might be four feet or twenty pieces of product.

Establishments must verify the reject mechanism speed and timing is set up to capture the entire implicated zone. The detection method is only as good as the reject mechanism. If the detector activates, but the reject mechanism does not function properly, corrective actions must be taken immediately. The reject mechanism also needs to reset in a timely fashion so that multiple rejects in a row can be captured. This can be verified through succession testing by passing standards through the detection equipment back to back. Many establishments choose to have an indicator to alert designated personnel when product is rejected, such as a light, alarm sound, or other notification. Although there are a variety of options, the most commonly used reject mechanisms in meat and poultry establishments include, but are not limited to:

BELT STOP

The detection equipment is linked to the conveyor, which will stop when FM is detected. Some systems are designed where an area employee is permitted to restart the conveyor, but others are locked out so only designated personnel can restart the conveyor. Product has to be physically removed by a human operator. It is critical for the human operator to understand the implicated zone for the detection system. Belt stops are typically used for products that can be easily picked up by a human operator, such as whole muscle cuts.

RETRACTABLE CONVEYANCE

The detection equipment is linked to the conveyor, which will retract, or shorten, to allow product to drop down into a container. The retraction is timed so the conveyor will lengthen back to its original position once the implicated product is rejected and subsequent product can continue through production. Retractable conveyance is typically used for products that are difficult to pick up by hand, such as trim, grinds, or diced products.

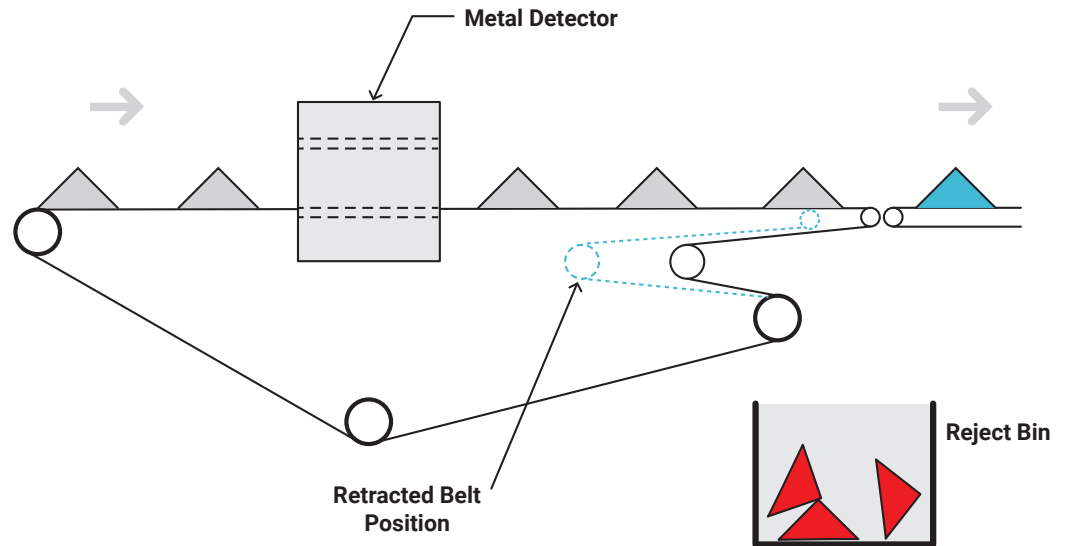


Fig. 3.14
Retractable
Conveyance
Systems

PIPELINE CONVEYANCE

Systems for pumpable, liquid, or slurry products apply the same concept as retractable conveyance. Implicated product is separated from the normal product stream into a container or alternate conveyance by a diversion valve.

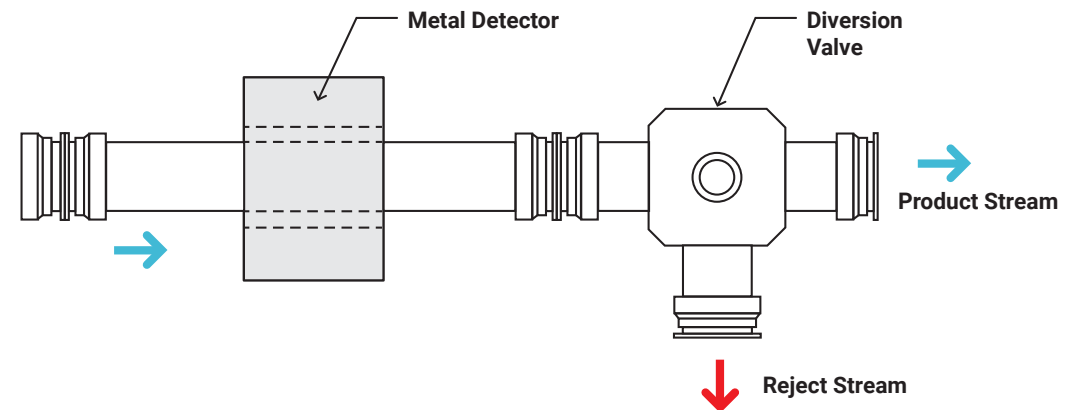
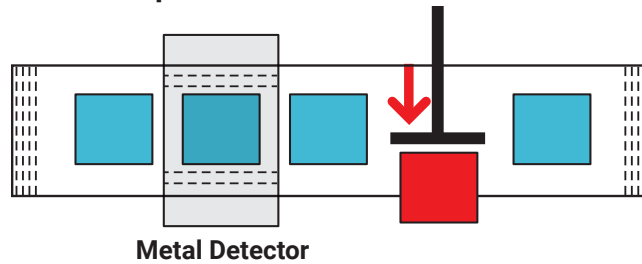


Fig. 3.15
Pipeline
Conveyance
Systems

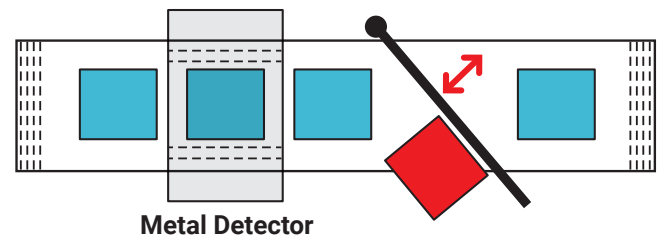
REJECTION ARM

The detection equipment is linked to a mechanical arm, which will push implicated product off of the main conveyor to an alternate conveyance or into a container. The arm is timed to return to its original position once the implicated product is rejected to allow subsequent product to continue through production. Rejection arms are typically used for more narrow conveyors where products are fairly spaced out and will not stick to the conveyor, such as packaged products. Different arm mechanisms may include pushers, sweepers, or diverters. *(examples in diagrams)*

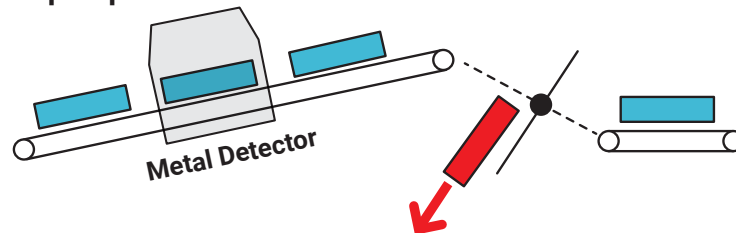
Linear sidepusher



Rotary arm



Drop flap



AIR BLAST

Similar to a rejection arm, the detection equipment is linked to a compressed air system, which will emit a strong gust of air to push implicated off of the main conveyor to an alternate conveyance or into a container. The air is timed to shut off once the implicated product is rejected to allow subsequent product to continue through production. Air blast is typically used for light weight products that will not stick to the conveyor, such as small, retail packaged products.

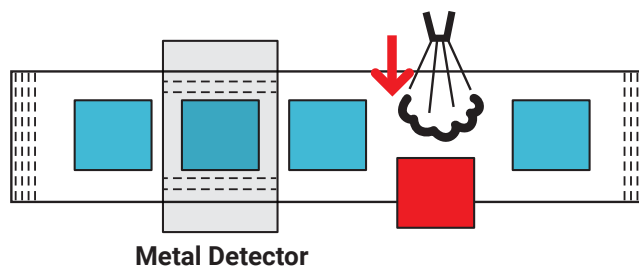


Fig. 3.16
Rejection Arms

Fig. 3.17
Air Blast

SUPPLEMENTAL TECHNOLOGY TO ASSURE REJECTION

There are various technologies available that can provide assurance that the reject mechanism functioned properly and verify other aspects of detection and rejection.

Although not required to implement an effective detection system, these technologies may enhance an existing system or be included in a new installation to allow for an automated reject verification process. There are many options available that should be discussed with the equipment supplier, some of which include:

- **Reject Verify Technology:** Photo eye sensors can be triggered upon detection to negatively verify product was removed by determining if there is a gap in the product flow. Sensors can also be used at the bin or the conveyor divert to positively verify that product was properly diverted. The sensors can trigger visual and/or audio alarms in the area, send notifications to key personnel, or a fault to stop the conveyance, or a combination of these options.
- **Fail Safe Conditions:** Sensors can verify the equipment is functional and that it operated as designed. If the equipment does not have sufficient air supply or the rejection arm does not retract after a reject it will not function properly. Alarms, notifications, or faults can be set up for low air, making sure the reject mechanism fired and reset, and other conditions.
- **Bin Full:** Sensors can recognize if the bin has enough space to allow rejected product with an alert to notify key personnel.
- **Redundant Rejection:** A secondary rejection system can operate to reject product in the event of a fault with the main rejection system.
- **Counters:** Some detection equipment can tally the number of detection events or a secondary counter can be integrated. The establishment can monitor this number to look for trends or verify the appropriate response was taken if the detection method was triggered.
- **Video Surveillance:** Cameras can be set up in the area for constant monitoring or to record upon detection. The establishment can verify the product was rejected and the appropriate procedures were followed by reviewing the recording.



Detection & Removal

The following methods are designed to detect and remove FM in one step.

MAGNETS

FUNCTIONALITY

Magnets produce a magnetic field that attracts other magnetic fields. In other words, only magnetic materials can be attracted to a magnet. If the attraction is strong enough, the magnet will “pull” the material to it.

FUNCTIONALITY FACTORS:

Type of material: Although all matter has some degree of magneticity, the FM must be magnetic enough to have a strong attraction to the magnet. Generally, in a meat and poultry establishment, this means metals or other metal detectable materials (plastics or textiles with trace amounts of metal embedded).

APPLICATION

Magnets are only effective when the FM can be pulled away and separated from the product, such as with powdered ingredients, liquids, or comminuted products that are not dense. The ability of the FM to flow through the product is key.

OPERATION

Temperature and impact, *i.e.* from being dropped, can damage a magnet and affect its pull strength. Establishments should regularly test using a dynamometer to ensure the magnet is achieving the pull strength recommended from the manufacturer.

CALIBRATION

Most processes will have some amount of particulate matter that is regularly picked up and considered normal. It may be beneficial to “calibrate” the process to determine what a normal amount of particulate matter is for the magnet. Establishments can monitor the magnet regularly using a white cloth to wipe the magnet to see what has been picked up and determine a baseline of the normal amount. It is important to avoid evaluating or removing particulate matter from the magnet over product zones.

SCREENS

FUNCTIONALITY

Screens create a physical barrier that prevents an object from passing through. Some systems will use multiple screens and/or a rework loop so that product can be reprocessed if the particle size of the product itself is out of specification.

APPLICATION

Screens may be effective in free-flowing product where the product is liquid or granular enough to pass through a screen and the FM is large enough not to pass through the screen. The screen size must allow acceptable product to pass and FM to be trapped. Placement of the screen(s) is key. In some processes a screen earlier in the process where an ingredient is added may be ideal, but in others it may be more effective to have a screen at the end as product is packed. Each establishment should consider the placement of screens specific to the process.

OPERATION

Screens can become damaged or worn overtime and should be regularly inspected to verify condition.

CALIBRATION

Screen checks should be conducted at a regular interval to observe the amount of matter sorted out. Matter may include out of specification product, product build up, or other particulate matter, including FM.

MANUAL VISUAL INSPECTION

FUNCTIONALITY

Manual visual inspection is still a common and effective method used in many establishments for various applications. Employees are trained to identify FM in a process by recognizing normal product variation. Employees may have to rotate, move, or otherwise manipulate product to observe all sides, or the process may have a mechanical solution.

APPLICATION

Employees can visually inspect product for various FM that may not be detectable in some other methods, especially unusual or novel types of FM. Employees must have a clear view of the product, either directly or through cameras, and the ability to remove or halt the process when FM is identified.

APPLICATION FACTORS:

Size and Orientation of FM: Employees can only detect FM that is large enough to see and not embedded in the product.

OPERATION

Many studies of human performance in inspection tasks have been conducted in the last 5 decades, although most of those studies have been performed in non-food production environments. The general consensus is that human inspection varies in its effectiveness, and can be significantly affected by effectiveness and can be significantly influenced by certain circumstances such as training, environment, engagement, and task difficulty.

Influence	Considerations
Training	Inspectors need ongoing training in order to be effective. Training should reinforce both how to find product defects (like foreign materials) and how to identify those defects. Training also needs to include specific instructions on what to do if a defect is found.
Line speed and the amount of material being inspected	As line speed increases and the volume of product increases, people's ability to inspect that material goes down. On the other hand, if the product is moving too slowly, boredom and second guessing may decrease performance and cause some inspectors to ignore possible defects.
Environmental conditions	Plant conditions like loud noise and cold (or hot) temperatures (which make people feel uncomfortable) will reduce inspectors' ability to detect defects.
The frequency of issues present	It may be surprising to learn that events that rarely occur are more likely to be missed by human inspectors. Issues like foreign material contamination (which don't happen very often) could be ignored or second-guessed by the inspector. This can lead to larger contamination issues or even recalls.

Fig. 3.18
Factors that may impact the performance of human inspectors.¹⁴



¹⁴ More information can be found at <https://ppo.ca/2020/04/03/are-food-inspectors-really-effective/>

OPERATION FACTORS:

Consistency: Employees have variable efficacy in detection and can suffer from fatigue, typically only being able to properly visually inspect for limited amounts of time. Establishments may rotate employees between visual inspection and other tasks to reduce fatigue, but this may increase variability.

Time: Research shows that human vigilance drops rapidly in inspection tasks over time.

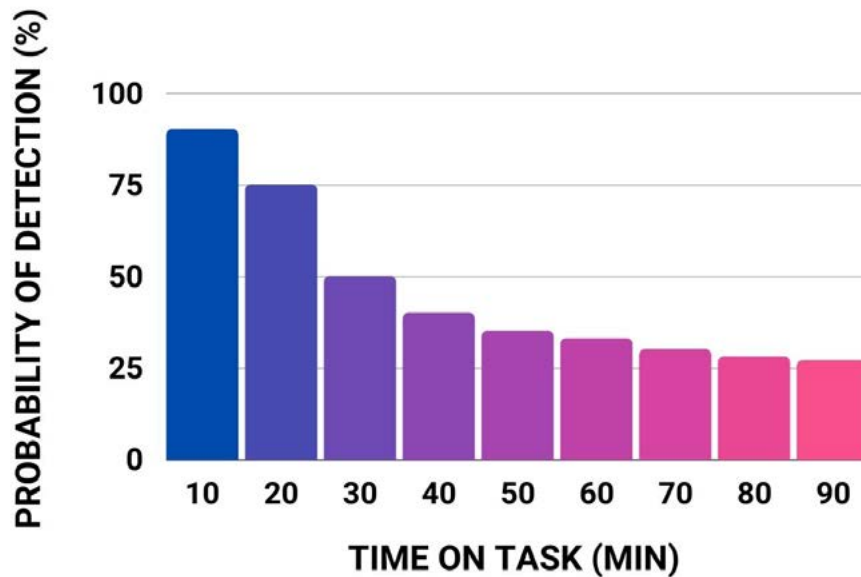


Fig. 3.19
The vigilance of average Human Inspector vs time on an inspection task.¹⁵

CALIBRATION

Verifying the effectiveness of manual visual inspection is difficult. Procedures using known standards, like those used with other detection methods, may not work.

Employees will likely see if someone introduces an object; therefore, it will not be an accurate test of their ability to identify FM. It may still be possible to do this kind of verification check without the employees seeing the object introduced, but care must be taken to ensure the object introduced is properly removed in the event it is not identified by the employees. Establishments may be able to use trending of customer complaints or internal findings to verify consistency and effectiveness.

¹⁵ Drury, G. Colin, and Jean Watson. 2019. "GOOD PRACTICES IN VISUAL INSPECTION."

HANDLING

Rejected Product

Once product has been rejected from a detection method, appropriate action should be taken.

What that action is will be determined by each individual establishment and may differ between detection methods, products, and processes. The point in the process where product is rejected is also key. If the establishment utilizes a multi-hurdle approach it may handle rejected product at the first hurdle differently than rejected product at the last hurdle. There is no set response to handling rejected product, but there are some common procedures to consider.

First, a method to physically segregate rejected product must be employed. This will be somewhat dependent on the detection method and the potential use of a reject mechanism, but some options include:

- Rejected product is handled by an area employee with specific training.
- Rejected product drops into a locked container that can only be accessed by designated personnel, using a key or passcode.
- Rejected product is automatically redirected through conveyance or other means.

Then, establishments should determine whether product should be discarded upon rejection. In some systems, immediate rejection may be preferred, possibly because the product is difficult or not worth the time to re-detect. Even if product will be discarded, it may be beneficial to inspect the product before disposal for the investigation.

For example, some establishments may rerun product through a detection system to identify any FM, but discard the product; even if no FM is identified or if FM is identified and removed, as an extra precaution.

If an establishment determines product should not be immediately discarded upon rejection, a process should be put in place to determine whether FM is present and if the product can be reworked. Some options include:

- Rejected product is pulled back before the detection equipment and rerun, possibly spacing the product out for improved detection, dividing it into smaller pieces, or changing the orientation.
- Rejected product is run through an offline detection system.
- Physically examine rejected product for FM.

Establishments may utilize a combination of these options.

Possible outcomes and responses could include, but are not limited to:

- **IF FM IS DISCOVERED:**
 - + Product is disposed,
 - + FM is removed and product is released, or
 - + FM is removed and product is reworked.
- **IF PRODUCT IS REJECTED MULTIPLE TIMES, BUT NO FM IS DISCOVERED:**
 - + Product is disposed,
 - + Product is inspected and released, or
 - + Detection system is adjusted or taken out of service.
- **IF PRODUCT IS NOT REJECTED AGAIN AFTER THE INITIAL REJECTION:**
 - + Product is released, or
 - + Product is inspected and released.

Establishments must choose the appropriate protocol for the process, products, and desired goal; and train employees accordingly.

If no FM is discovered, a false positive may have occurred. With some systems, a certain number of false positives is expected. If the rate trends higher than normal, the detection system should be evaluated and may require adjustment or repairs before further use.

If FM is discovered, it may trigger an investigation and corrective actions, but, generally speaking, if a detection method identifies FM it was designed to weed out as part of a control step, there is no failure.

The process operated as designed. However, if the detection method discovers an excessive amount of FM or a different type or size of FM than it is designed to target, it may constitute a finding.¹⁶

Establishments should consider how they will respond to findings, both of targeted and novel FM, when determining what detection method(s) to implement. For more information see the response section.

¹⁶ **REGULATORY REQUIREMENTS:** There may be associated regulatory requirements if the FM is determined to be a hazard. For example, in the US, if the finding represents an unforeseen food safety hazard 9 CFR 417.3 applies.

DETERMINING Location

DETERMINING LOCATION

There are various points in a process where detection methods may be applied.

The appropriate location should be evaluated on a case by case basis, informed by the risk assessment. Establishments should have an intended outcome in mind.

For example, if the goal is to prevent FM from entering equipment and causing damage or being distributed through the equipment, a detection method should be used before the equipment.

If detection is being used as verification for raw materials, it should be used for those materials, prior to comingling or introduction into product. Temperature may also play a role. Some detection methods are more effective with frozen product. However, there are typically more options with fresh product for rework and corrective actions in the event of a finding.

The type of detection and reject system may also impact location based on size or feasibility. Some detection methods will not be compatible or as effective with larger products and are best applied after the product size has been reduced through processing. The establishment may not have room to put in a certain detection or rejection system, but another system may fit. The system also needs to be accessible for maintenance, monitoring, and sanitation.

Ideally, detection should be conducted as early in the process, as close to the potential introduction point as possible. However, establishments may have to balance this with the factors mentioned, as well as other considerations. For example, if similar FM can be introduced at multiple points, a more cost-effective option would be to have the detection system after all of the possible introduction points. Although, this might also be a potential use of the multi-hurdle approach.



Verification

VERIFICATION

Establishments should regularly verify the effectiveness of detection methods.

When determining the frequency to conduct verification checks, establishments should consider the amount of product that may be implicated between each check.

Generally, if the verification check shows the detection method failed, all the product that passed through up to the last acceptable check would be in question. A company may have re-run product through the detection system once it is working properly or use an alternate detection method to re-inspect the product. It will be important to consider the how much product the establishment is willing or able to control and re-inspect in the event of a failure.

Additionally, once a verification frequency is determined the establishment should continue to re-evaluate the chosen frequency regularly and keep record of the failure rates for subsequent assessments.



4



RESPONSE

4

PART FOUR

Response

Although FM incidents can be reduced, it is unlikely they will ever be completely eliminated.

An effective response to an incident is a key function of a FM CPP. There are two main types of FM incidents: events and findings.

- **AN EVENT**

is where something occurs, typically within the facility, that signifies a potential for FM to have been introduced into product. Examples of events include malfunctioning equipment, wear on equipment or tools, and missing or damaged PPE or tools.

- **A FINDING**

is simply when FM is discovered within the facility prior to product shipping or by the customer. It is important to differentiate between a true finding and FM that is eliminated through a detection method. If the detection method is put into place to eliminate that type of FM, then FM detected at that step may not be true findings. Instead, the FM may be evidence that the detection method and process is functioning as designed. However, if the detection method discovers an excessive amount of FM or a different type or size of FM than it is designed to target, it may constitute a finding. It is important to analyze FM discovered through detection methods to determine whether they are true findings. If a detection method was put into place for process improvement, detection of FM does not necessarily mean the process is out of control, it may simply be functioning as designed.

There are several parts to a response, some of which will happen simultaneously, although not all of the parts provided will be necessary for every incident and may not be completed in the order the information is presented.

Establishments might consider conducting a mock exercise to practice the response process before an incident occurs.

ESTABLISH A Response Team

RESPONSE

Whether responding to an event or a finding, having **a comprehensive, multidisciplinary team** can be crucial to a successful resolution.

Establishing a core team before an incident occurs will promote a speedy response, although the players may alter depending on the expertise needed for a particular incident. Elements to consider include:

- A designated person or group and their backups within the core team should be responsible for triaging information and coordinating the response team, determining if additional members are needed beyond the core team.
- Contact information for the core team members and their backups should be kept up to date and accessible.
- The core team should be made up of individuals from various departments or roles in the operation. Although most establishments coordinate the response team through the quality assurance department, other key team members may include production, sanitation, maintenance, or procurement.
- Team members should also represent all relevant time periods, such as nights or weekends, to ensure key aspects are not overlooked and different levels, such as line workers and various levels of management. For example, if the only maintenance personnel on the team is a supervisor that works weekdays, but there was work done over the weekend by a technician that impacted the incident, key information may not be identified in a timely fashion.

For findings reported to the establishments by customers or other outside sources, a subset of the response team or another designated party should triage the information to determine its validity and whether a full investigation is appropriate.

For example, an establishment may receive a complaint on a product allegedly containing FM that the establishment does not produce or might not receive enough information to properly investigate. It would not be prudent to expend resources on false or unsubstantiated complaints.

Note: For more information on responding to findings reported by customers and regulatory requirement for reporting incidents, reference the [Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products](https://www.meatinstitute.org/ht/a/GetDocumentAction/i/152996) at <https://www.meatinstitute.org/ht/a/GetDocumentAction/i/152996>

Control Product

RESPONSE CONTROL PRODUCT

Controlling product as early as possible can be **crucial** to limiting the impact of an incident.

An event will often trigger the need to control product, but it is possible that a finding, especially multiple findings of the same type of FM, could identify the potential for more product to be affected.

When determining what product to control, it is advisable to cast a wide net based on the worst-case scenario early on. Product can be released if the investigation establishes a narrower scope, but it is often difficult to widen the net later in the process. There are several things to consider when determining the scope of product to control.

- All components of a lot of raw materials. If the FM could have come from a raw material lot, all of that lot should be captured, including other finished or WIP products that used the same raw material lot.
- All components of the product, such as packaging, dry ice, ingredients, water, ice, brine, etc.
- Whether the FM was introduced through raw materials received from an outside establishment or if it could have been introduced internally. If the FM was introduced internally, consider the potential impact for other products produced on common equipment. If the FM source is a supplier, consider notifying sister establishments, where applicable.
- If responding to an event where material is missing, verify that it was potentially introduced into product and cannot otherwise be accounted for. For example, it may have been misplaced, thrown away, or rejected. This is an aspect where the multidisciplinary team will play a key role.
- Any rework that went into the product or any of the product that was reworked into other products. This will also inform whether the investigation needs to cover the rework process in addition to the normal process.
- The likelihood of intentional adulteration. If the FM was introduced intentionally, it may provide insight on the scope.
- Whether the incident is isolated or systemic. If there are multiple findings of the same or similar FM or the event could have produced multiple pieces of FM spread over a longer period of time, the incident may be systemic. Further investigation and root cause analysis will help determine whether the incident is systemic, which may not be able to be completed before product needs to be controlled. Establishments should err of the side of caution initially. See sections on investigation and root cause analysis for more information.
- Time.



The time period associated with the incident is often the most difficult aspect to determining the scope of product.

Establishments should identify the “**bookends**” of an incident with the start time being when the incident did or could have begun to impact product and the end time of when product would no longer have been impacted.

TIME can be broken down in many different ways, such as by:

- combo
- lot
- production shift or day
- cleanup to cleanup

Other information might also provide exact times, such as video monitoring or documented equipment checks. When relying on documented checks, it is recommended to control product back to the last acceptable check before a failed check or incident. Again, further information may allow for the scope to be limited or cause it to be expanded, but the last acceptable check is generally an appropriate place to start.

Time studies can provide critical insight on how long it takes for product to move through an area.

Other studies can be conducted to determine whether the flow of product ensures that FM is removed along with the product. For example, if FM is introduced in a mixer, it might be possible for some of the FM to be left behind in the mixer after the product is emptied.

In some situations, it may be helpful to initiate cleaning if an end time cannot be determined. This may serve to restore sanitary conditions and establish a precursory end time, preventing further product from being implicated; even if further investigation shows the cleaning was not necessary and/or an earlier end time is determined.

Once product has been identified that should be controlled, the establishment should act quickly.

Multiple levels of verification are recommended to ensure the correct type and amount of product is controlled. Controls may include visual holds, physical holds, electronic holds, or, preferably, a combination.

- **VISUAL HOLDS** are where product is marked in a way to designate it is not eligible to ship, such as brightly colored hold tags or tape.
- **PHYSICAL HOLDS** are where product is stored in a manner where only designated personnel can access it to prevent it from being shipped, such as a locked cooler or cage within a cooler.
- **ELECTRONIC HOLDS** are where product shows up as not eligible for shipment when scanned to be added to a load.



Establishments should periodically verify that product remains under control until it is released. Outside or third-party warehouse control protocols must also be verified as effective, preferably before an incident that requires product to be held and on a regular basis after implementation.

Investigate

PHYSICAL OBSERVATIONS

The value of a robust, hands-on investigation cannot be overstated.

It is important to physically walk the entire process using organoleptic inspection: looking for damage or missing pieces and listening for rattling or other abnormal noises. This is another aspect where a multi-disciplinary team is key. An individual who does not typically work in the area may see something overlooked by area employees, but someone who knows the area well may be able to easily identify something is different. Surrounding areas not directly involved in the process should also be considered; along with related areas, such as equipment storage, a maintenance parts room, or an employee PPE station.

If all pieces can be accounted for by matching a finding back to damaged materials or locating all missing pieces from an event, the response becomes much simpler.

For example, if a piece of equipment, PPE, or tool breaks, all of the pieces can be collected and put back together like a puzzle. If it is clear that there are no missing pieces, then everything is accounted for.

It is likely that product can be released and production can resume, if it was deemed necessary to stop production for the investigation and once any repairs or replacements are made, as needed.

INTERVIEWS

During the walk through or as a follow-up, the response team should interview area employees.

Establishments often think to speak with the area supervisors and management, however, the employees doing relevant work at the time of the incident may be a critical resource. Consider speaking with individuals such as the line worker next to relevant equipment, the quality assurance technician conducting an audit of the product, the sanitation employee in charge of the area, or the mechanic that performs routine maintenance on the equipment.

The response team should ask about:

- process changes
- new equipment or tools
- key personnel that may have been absent
- visitors in the area
- any other unusual observations

If the incident was reported by a customer; if possible, they should be interviewed for relevant information. If available, the establishment should request the FM be collected or shipped back to the establishment. The value of being able to physically touch, examine, and compare the FM is crucial, because photos and descriptions may not represent the FM well. If the FM cannot be provided, as much information as possible should be requested on the FM, with photos that have a reference object to establish relative size, *i.e.* ruler, coin, etc.

Important information to gather includes, but is not limited to:

- When and how the FM was discovered and its location relative to the product.
- Details about the product, such as
 - + the brand name
 - + description
 - + lot code or date
 - + establishment number
 - + packaging information
 - + purchase location
- If the customer is a further processor, it is important to understand whether products were commingled.
- If the customer is a consumer, it may be helpful to know if the product was prepared before the FM was discovered and, if so, how it was prepared.

All of this information can be helpful to first substantiate the complaint as well as aid in the investigation.

Note: For more information on investigating customer complaints, reference the [Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products](https://www.meatinstitute.org/ht/a/GetDocumentAction/i/152996) at <https://www.meatinstitute.org/ht/a/GetDocumentAction/i/152996>

RECORDS REVIEW

A review should be conducted of all relevant records, not just HACCP or quality assurance documents.

Maintenance, operations, safety, or sanitation records may contain critical information. It may be beneficial to review the records kept by various departments in advance of an incident so the response team knows the type of information available for an investigation. Video records from video monitoring or surveillance systems may also be useful.

The records review should include information regarding raw materials, ingredients, packaging, or other materials. This may lead back to additional physical observations of receipt and handling to determine whether the FM could have been introduced through materials. If the investigation reveals a material as a potential FM source, the supplier should be contacted to investigate and provide feedback, including corrective actions where appropriate, to the establishment.



CONDUCT A Root Cause Analysis

RESPONSE CONDUCT A ROOT CAUSE ANALYSIS

Following the initial investigation, it is important to conduct a thorough **root cause analysis** (RCA).

There are many well-established tools for conducting an effective RCA. Establishments should utilize the tool that works best for their management style and process.

If unfamiliar with a particular tool, the **“5 Whys”** system is a viable option. “5 Whys” uses a series of questions asking why to determine the underlying reason for a problem, past superficial layers. Establishments start with an initial question of why and the resulting answer becomes the root of the next why question. It may not take all five “whys” to get to the root cause or it may take more. No matter the tool, the intent is to dig past the initial quick response to find the true origin of the issue to ensure a sustainable preventive measure can be implemented.

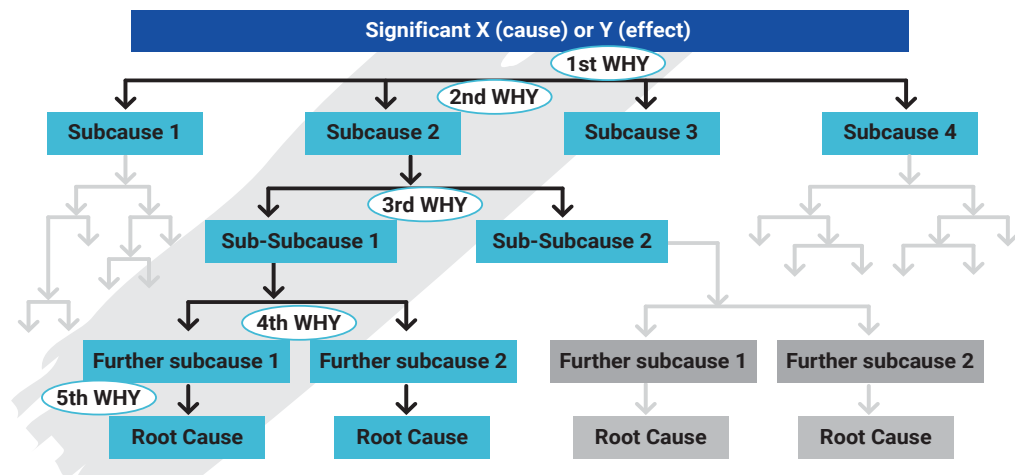


Fig. 4.1
5 Whys System

Note: Another common option is a fishbone diagram. The American Society for Quality provides online resources on this technique¹⁷, as well as more information on the 5 Whys.¹⁸

Inevitably, even with a thorough investigation and RCA there will be times when the root cause cannot be identified.

There may be critical information that is not available or the FM may not match any materials within the establishment, among other potential issues. However, establishments should only make the determination that a root cause is unidentifiable after due diligence. In that case, the investigation should be well-documented and accessible in case additional information becomes available at a later time or a similar incident occurs. Even without a root cause, there may be learnings that can translate to preventive measures or process improvements.

*See Addendum E for an example scenario and Addendum F for tips and learnings from industry professionals to consider for specific situations.

¹⁷ Fishbone Diagram Technique resources at <https://asq.org/quality-resources/fishbone>

¹⁸ 5 Whys System resources at <https://asq.org/quality-resources/five-whys>

Classification

Incidents should be classified to ensure the appropriate response is initiated.

Findings can be classified by assessing the FM itself, but events may have to be preliminarily classified by the potential FM unless and until FM is discovered.

Establishments may utilize an individualized classification system, but there is one standard classification all establishments must consider: food safety hazards. Beyond classifying food safety hazards, establishment may designate incidents into categories, such as sanitation, quality, or customer requirements. The response for a food safety hazard will likely be much different than the response for a quality issue.

FOOD SAFETY HAZARDS

The public health risk of FM typically falls under either: INJURY or CHOKING HAZARD.

Injuries might include a broken tooth or a laceration in the mouth or GI tract, so the hardness and sharpness of the FM is key. Choking hazards are more likely when the FM can become lodged in the airway, so the size and shape are key. For all FM the location, size, and intended use of the product are critical. There are several things to consider when determining whether FM represents a food safety hazard:

- **Intended Use:** Products that will undergo further processing are lower risk than those intended to go directly to consumers via retail or foodservice. Certain consumers are also at higher risk for injury from FM, such as small children where FM may be more likely to pose a choking hazard.
- **Size:** Objects smaller than 7 mm in all dimensions are likely to pass through the digestive tract without posing a choking hazard. The same is true for objects smaller than 2 mm in every dimension for children and infants.¹⁹ Objects larger than 25 mm are likely to be discovered prior to damage or swallowing.
- **Shape:** Spherical or similarly shaped objects are more likely to become lodged in the airway. Sharp objects are more likely cause lacerations.
- **Consistency:** Hard objects are more likely to damage teeth during chewing or be firm enough to cause lacerations. Soft materials that break down during chewing will likely not constitute a physical food safety hazard. Certain softer materials may still pose a choking hazard if they do not break down during chewing, if other aspects are consistent with choking hazards.
- **Location:** FM on the exterior surface of the product where it can be identified and removed prior to eating is likely not a food safety hazard. Embedded FM, such as FM deep in the muscle tissue or underneath the breading layer, is more likely to pose a public health risk.

¹⁹ Health Canada considers 2.0 mm or greater as the size threshold for consideration as a health risk. [Health Canada. Field Compliance Guide 90-2, Subject: Injurious Extrinsic Material. Ottawa: Health Products and Food Branch, Health Canada, 1990.] <https://active.inspection.gc.ca/rdhi-bdrid/english/rdhi-bdrid/introe.aspx?i=8>

Public health and regulatory communities generally agree that hard or sharp foreign objects between 7 and 25 mm in any dimension are considered to be a food safety hazard, except for in sensitive populations where hard and sharp objects between 2 and 25 mm are considered a food safety hazard. However, establishments should thoroughly evaluate FM to determine the potential risk.

Establishments should also consider additional risks posed by the FM other than physical hazards. FM may introduce chemical or biological hazards that should be evaluated.

OTHER CLASSIFICATIONS

FM that does not constitute a food safety hazard can be further classified to help drive the appropriate response and aid in trending.

Establishments may classify FM as a sanitation concern if it is insanitary or creates an insanitary condition, such as wood from a pallet. FM may be classified as a quality concern if it is not a food safety hazard and is not insanitary, such as a clean, intact meat hook. The other classifications used by establishments are variable and dependent on how the data will be utilized.

Note: Although establishments are at liberty to categorize incidents for their own management and trending purposes, corrective actions must be completed per FSIS regulations. See note in Corrective Action Section.

Incident Risk Assessment

The investigation, RCA, and classification should provide all the information needed to conduct a risk assessment and many aspects may already be completed during these other stages.

A risk assessment is likely to be conducted alongside the other response steps, simultaneously.

As discussed in the beginning of the manual, risk assessments are the foundation of a robust FMCPP and should be conducted upon any significant change. The earlier section may be useful in conducting an incident risk assessment; however, this particular application of a risk assessment is different than a system risk assessment. An incident risk assessment is conducted to inform the decision-making process for product disposition, corrective action, and preventive measures.

Establishments should utilize the risk assessment process that works best for their process and may delineate risk into more or different categories than the two-tier approach provided here.

Early on in the response process it should hopefully become evident whether the incident represents or has the potential to represent a food safety hazard. These incidents would fall under **Tier 1**, where all other incidents would fall under **Tier 2**.

- **Tier 1 Incidents** represent a food safety hazard or the potential for one. They are considered higher risk and require an immediate and rigorous response. Establishments should utilize the worst-case scenario when determining the scope of product and the proper disposition.
- **Tier 2 incidents** do not have the potential to represent a food safety hazard. They are considered lower risk and the response is not as urgent. Establishments should make decisions in the best interest of the company based on the information at hand and the willingness to accept risk. For example, even if the risk is deemed very low, a company may decide to take a conservative approach and remove more product than might be necessary from commerce as a precautionary measure.

Regardless of the tier, the establishment must be able to support its decision and demonstrate that adulterated, unsafe, or probably unsafe products are accounted for and either not in commerce or removed from commerce.

DETERMINE Disposition

Using the information gathered during the investigation, RCA, classification, and/or risk assessment the establishment must determine what to do with controlled product.²⁰ Disposition decisions are not solely based on product risk and often include considerations on quality, cost, logistics, etc. The following are common product dispositions, but there are many others that may apply:



Release: when product is determined to pose no, or an extremely low, risk. Potentially because the incident was determined to be isolated or all missing pieces have been accounted for, along with other scenarios.



Rework: when product may be at risk and the rework process might be able to reduce or eliminate the risk. Rework may include, but is not limited to, sending product through a detection system, visual inspection, trimming, or reprocessing. If the rework process is determined to reduce or eliminate the risk sufficiently, product will likely be released. However, product may require additional evaluation after rework, depending on the situation.

²⁰ In some cases, a statistically valid sampling plan may help support an establishment's disposition in combination with supporting evidence from the investigation.



Send for Further Processing: when product may be at risk and a further processor might be able to reduce or eliminate the risk sufficiently. The potential risk must be communicated to the further processor and products controlled through the shipping process.



Render: when product is not fit for human consumption or does not meet customer expectations, but fit for rendering. Establishments should also consider the customer expectations and regulatory requirements for rendered products.²¹ The rendering process can eliminate many types of foreign materials, but the establishment should evaluate the capabilities of their rendering system and any customer requirements. Establishments that utilize third party rendering should be aware of the receiving requirements.



Dispose: when product is not fit for human consumption or does not meet customer expectations it may be permanently disposed of, such as by diversion to a landfill, incineration, etc. Potentially because the product is believed to contain FM or is aged past its usable date during the investigation process, along with other scenarios.

Not all product will necessarily have the same disposition. **For example**, if the investigation revealed a narrower scope than originally held, some product may be released and only product from the confirmed, narrower scope may be reworked.

Establishments should record the disposition and relevant details for all incidents. However, records may be especially important for product that is reworked, sent to a further processor, or disposed of, to provide evidence to regulators.

Trending

Tracking and **trending** FM incidents can provide useful information in decision making processes, such as reassessments.

Trend data may also signal a major event. **For example**, if there are multiple findings of similar material in the same product from the same line spread out over time.

If the establishment is not tracking the findings, each incident may seem isolated if there is enough time in-between. The trend data may signal the potential for a larger event causing intermittent findings.

²¹ **REGULATORY REQUIREMENTS:** If destined for animal feed, the Preventive Controls for Animal Food regulations under the Food Safety Modernization Act apply. 21 CFR 507

Establishments should always document incidents and should consider using the information gathered through the response process to establish baselines, identify trends, etc. Establishments will determine which data points are important to track, but might consider some basic elements:

- **FM TYPE** either by material, such as plastic, metal, wood, or glass; or more specifically, such as belt, glove, packaging, etc.
- **FM COUNT** of pieces found or missing, which may be an indicator of severity
- **LOCATION** can be as general or specific as appropriate.
- **PRODUCT** using general groupings or specific product numbers.
- **DATE AND TIME** looking at the day of the week, month of the year, shift, period, etc.
- **QUANTITY** of product implicated, typically measured in pounds, but could also use cases, packages, carcasses, etc.
- **SUPPLIER** if the incident stems from received materials.

For example, tracking quantity can help provide insight into which incidents have the greatest impact and demonstrate the best use of additional resources, such as equipment upgrades or installation of a detection system.

Additional details about the FM itself or the incident may prove useful to track, dependent on the establishment. However, an easily managed tracking program is more likely to be consistently implemented. Meaningful and useful information may get lost if too much information is tracked. Depending on the establishment, processes, and findings over time, each program should be designed and adjusted to be the most impactful.

These programs should be a living document that is modified over time as learnings are made and insights are gained. Helpful in this regard, the use of Microsoft's PowerBI²² or a similar tool using pareto chart or graphs is a good tool to visualize trends, but a sophisticated analysis may not be appropriate for smaller establishments or those with few incidents to track.



²² Information can be found at <https://powerbi.microsoft.com/en-us/>

Corrective Actions, Preventive Measures, and Reassessment

RESPONSE CORRECTIVE ACTIONS

There are three levels of measures designed to correct and further prevent the same or similar incident.

They are commonly referred to as immediate corrective actions, preventive measures, and reassessment.

Although some incidents will require all three, one or two may be sufficient.²³

IMMEDIATE CORRECTIVE ACTIONS

should be implemented as soon as possible to ensure the incident is controlled and prevent additional product from being implicated. Immediate corrective actions do not need to be permanent solutions, although it is possible they may be, and may include several steps. The measures should provide clear assurance that the incident has been controlled. Possible immediate corrective actions may include one or more of the following, although there are many more:

- Taking the implicated equipment offline;
- Repairing or replacing equipment, parts, tools, and/or PPE;
- Cleaning and sanitizing the area;
- Increased monitoring;
- Temporary repairs; and/or
- Putting a temporary barrier in place.

²³ **REGULATORY REQUIREMENTS:** Establishments must conduct corrective actions in accordance with 9 CFR 417.3(a) or (b), depending upon whether the finding is foreseen or unforeseen food safety hazard. Incidents that do not represent a food safety hazard and are not related to the HACCP plan must be handled in accordance with 9 CFR 416.15. Although these incidents may not logically fall under "sanitation" or be associated with establishment SSOPs, actions that meet the requirements of 9 CFR 416.15 are still required, because all FM is considered to be an adulterant. Sufficient corrective actions are essential for a prerequisite program to continue supporting the determination that a hazard is not likely to occur, as required by 417.5(a)(1).

PREVENTIVE MEASURES

Preventative measures are best implemented after the root cause analysis has been conducted to ensure the measures will effectively address the core aspect of the incident. Immediate corrective actions may need to remain in place under permanent preventive measures can be implemented. Often, the best preventive measures are concrete changes to the process, equipment, or procedures. Such measures typically offer the best protection from subsequent incidents.

Although tangible measures are ideal, employee training or disciplinary action may be appropriate in some circumstances. Training should be primarily reserved as a preventive measure only for novice employees, those not fully trained, or as part of the preventive measures as a result of a procedural change. If the root cause analysis reveals that employee error contributed to the incident, establishments should consider whether the employee was properly trained. It might be necessary to make improvements in the training methods, materials, or evaluate the trainer(s).

Training is not an appropriate measure for experienced employees who fail to follow adequate training. The investigation should identify whether there were barriers preventing the employee from following the appropriate protocols. Barriers such as a safety concern or physical hindrance may be addressed with concrete measures.²⁴ If it is determined that the employee willfully disregarded protocol, disciplinary action may be appropriate. Establishments should follow internal disciplinary procedures, in accordance with state, local, and union requirements, where applicable.

Increased monitoring may be an appropriate immediate corrective action in some circumstances, but it should rarely be used as a preventive measure.

Monitoring does not truly correct an issue and prevent additional incidents, it only serves to ensure future incidents are properly identified. However, increased monitoring may be appropriate if the source cannot be identified. Establishments should still consider additional preventive measures in conjunction with increased monitoring and implement more concrete measures if the source is eventually identified.

When the investigation reveals a received material(s) contributed to the incident, the supplier(s) should be responsible for respective aspects of the response: predominantly preventive measures. Adequate information should be relayed through the supply chain in a timely fashion to allow a thorough investigation and response from the supplier(s). This may include communication through brokers or other parties.

²⁴ **REGULATORY REQUIREMENTS:** For more information on training, see the [Prevention Section](#).

The establishment should request a written response that provides relevant details of the investigation, corrective actions, and preventive measures. Depending on how a supplier responds to an incident, an establishment may choose to request additional measures, perform verification to ensure the issue is resolved, or change suppliers, among other possibilities. However, drastic actions might be best reserved when multiple incidents have occurred or the incident is particularly severe. It may be unclear which supplier is at fault, because there are several suppliers providing the same or similar materials, such as with live animal receiving. Information should still be relayed back through the supply chain to all suppliers potentially involved, although it is likely not reasonable to expect a response. This allows prudent suppliers a chance to take proactive measures, even if they were not directly responsible for the incident.

REASSESSMENT

Reassessment may not always be necessary. It should be conducted if the incident represents a significant failure or deficiency of the FM CPP or a repetitive issue that previous measures have not resolved.²⁵ The establishment may also elect to reassess when other factors suggest it is prudent. Reassessment may be limited to a single program, procedure, or element of the FM CPP; the FM CPP in its entirety; or the HACCP system, in whole or in part. The earlier section on risk assessments may be useful in a reassessment.

²⁵ A HACCP reassessment is required by regulation in the US when the incident represents an unforeseen food safety hazard or could affect the hazard analysis. 9 CFR 417.3(b) and 417.4(a)(3)(i).
A HACCP reassessment is required in Canada when situations occur that could affect the hazard analysis. CFIA Food Safety Enhancement Program Manual.

5



ADDENDA

ADDENDUM B.

An abbreviated comparison of detection methods. Detection systems are unique and should be evaluated on a case by case basis. This provides a general overview of the capabilities and limitations of the current technology, but there are always nuances and exceptions. See the Detection section for more information on a specific method and contact the manufacturer for specific information on a particular system. *Not necessarily considered FM, but included for reference.

Detection Method	Detectable FM	Example FM Sources	Detectable Product Examples	Limitations	
Metal Detector	Metal (ferrous, non-ferrous and stainless steel)	Equipment, parts, tools, hooks, needles, buckshot, metal wire ties	Fresh or frozen cuts, ground, processed, cases, packaged, or prepared meals	Glass, wood, plastic, textiles, etc. (unless embedded with metal for detectability) are undetectable; Non-magnetic stainless steel is the most challenging metal to detect	
X-Ray	Metal (ferrous, non-ferrous and stainless steel)	Equipment, parts, tools, hooks, needles, buckshot, metal wire ties, blade tips	Frozen or fresh cuts, ground, processed, packaged, cases, or prepared meals	Lower density materials, such as wood, paper, aluminum foil, plastic, rubber, etc. are less likely to be detected; Bone detectability is based on calcification, making poultry bones more difficult to detect than pork or beef. Dual energy is suggested for targeting bone.	
	Plastic (PVC & Teflon)	Wire insulation, gaskets			
	Glass	Light, glass tools or parts, measuring equipment, raw materials			
	*Bone(Calcified)	Inherent			
	Rubber	Gasket Materials			
	Mineral Stones & Rocks	Debris from agricultural commodities			
Vision System	Camera	Plastic	Hot dogs, nuggets, patties, or ground beef	Embedded objects are undetectable; FM similar in color to the product and very small or hard to see pieces are challenging to detect; Complex product surfaces or textures and glare from wet surfaces may decrease detectability.	
		Bone			Inherent
		Wood			Pallets
	Multispectral	Plastic	Equipment, parts, casings, gloves, packaging, liners, bins	Bacon bits, cuts, or nuggets	Materials not identified during calibration and embedded or very small FM are difficult to detect.
		Bone	Inherent		
		Mineral Stones & Rocks	Debris from agricultural commodities		
	Hyperspectral	Plastic & Glass	Equipment, parts, casings, gloves, packaging, liners, bins, films, shrink wrap	Various cuts, bacon bits, ground products, nuggets, patties, or liquids	Very thin transparent films and embedded, very small, or highly reflective FM are difficult to detect.
		*Bone, Cartilage, & Tendons	Inherent		
		Inorganic Impurities	Equipment, parts, tools, hooks, needles, buckshot, metal wire ties, blade tips, safety glasses, rocks		
		*Organic Impurities	Fecal matter, bugs, cardboard, paper, wood, fibers, well established biofilms, specified types of meat, fat, lean		
Magnet	Metal (magnetic)	Equipment, parts, tools, needles, buckshot, metal wire ties	Fluids, spices, or free-flowing, pumpable, or finely comminuted products	Glass, wood, plastic, textiles, etc. (unless embedded with metal for detectability) are undetectable; Not effective for dense products such as raw grounds, deli products, or cooked products like hams or roasts.	
Screens	Large Contaminants (metal, plastic, glass, wood, rocks, etc.)	Equipment, parts, tools, pallets, debris from agricultural commodities	Spices, flour, beans, liquids, or meals	Whole muscle products, large products; FM smaller than the screen size will not be detectable.	
Manual Visual Inspection	Large Visible Contaminants (metal, plastic, glass, wood, etc.)	Equipment, parts, tools, pallets, plastic, textiles	Cuts, trim, or other products with high visibility, presentation is more important than product type	Generally not effective for grounds, comminuted products, liquid, or packaged products.	

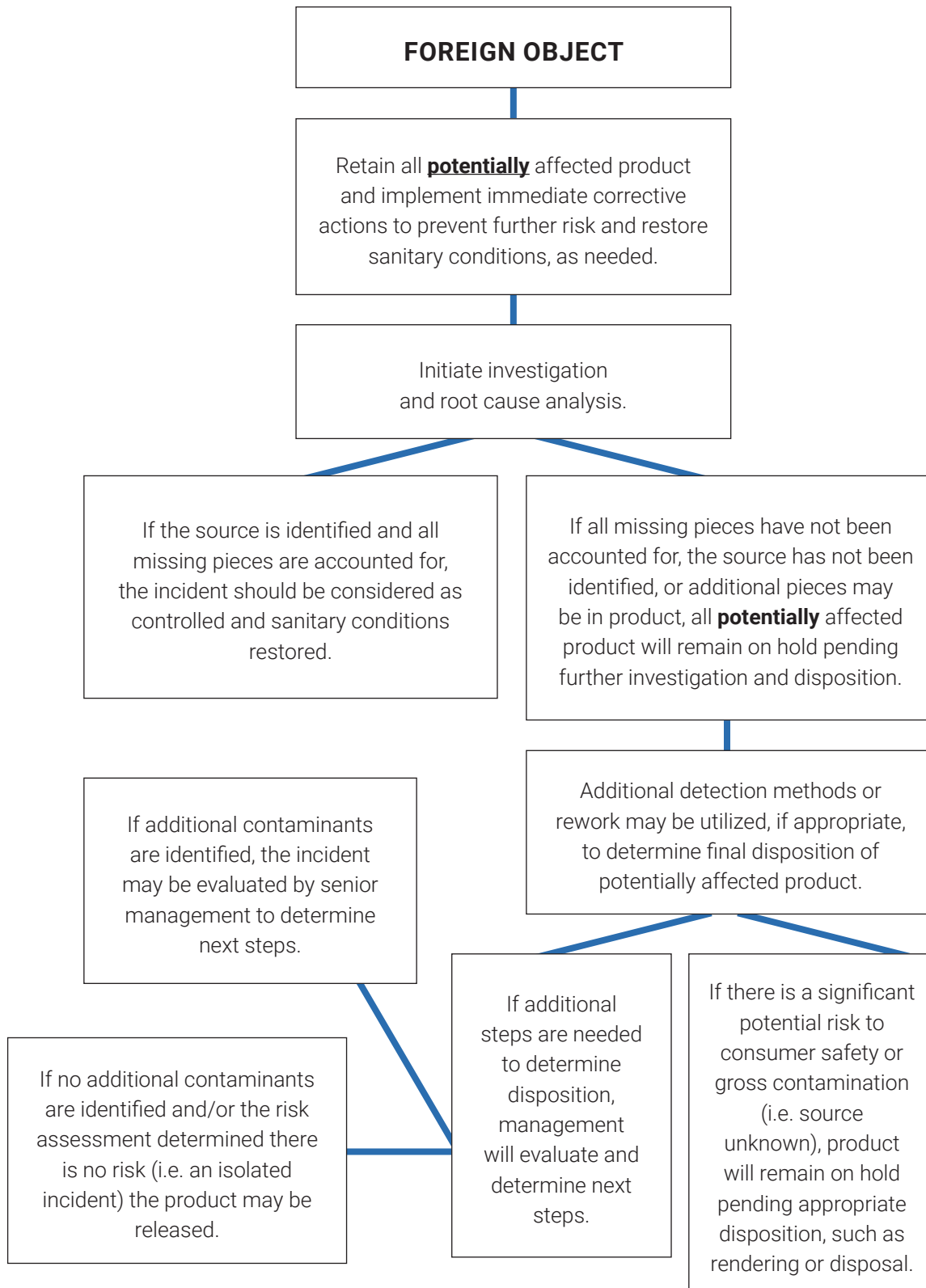
ADDENDUM C.

An example checklist an establishment may use to help navigate through an incident. An establishment may elect to modify this worksheet or develop its own.

<input type="checkbox"/>	<p>STOP the impacted process as needed.</p>	<p>Timely action is important to control the incident or else more product will get impacted.</p>
<input type="checkbox"/>	<p>ENGAGE Management & FSQA immediately.</p>	<p>Engage relevant personnel such as Production Management, Sanitation Management, Maintenance Management, FSQA, area personnel, contractors</p>
<input type="checkbox"/>	<p>EVALUATE the scope and magnitude of the incident. Is this isolated, intact, or widespread?</p>	<p>Are all the pieces from the incident accounted for? This evaluation may include, but is not limited to:</p> <ul style="list-style-type: none"> • Product & process flow • Raw material and dump/tank logs • Equipment checks (belt inspections, grinder tear downs, needle checks, injector checks, etc.) • Surveillance Camera footage • Relevant line worker interviews • Maintenance repair logs • Supply issuance records for equipment, parts • PPE & tool tracking • Detection logs (metal detectors, X-rays, screens, magnets, etc.) • Packaging records • Ingredient logs
<input type="checkbox"/>	<p>CONTROL ALL potentially affected product. Be conservative and capture more rather than less. Product can always be released later.</p>	<p>Consider</p> <ul style="list-style-type: none"> • raw materials • ingredients • WIP products • by-products • marinade or brine • finished products • packaging materials
<input type="checkbox"/>	<p>DETERMINE PRODUCT DISPOSITION If not up to last acceptable check then support decision for the narrower affected lot.</p>	<p>Rework ALL the potentially affected product through a method that is sensitive enough to find the object(s) of concern. ALL missing pieces must be accounted for through rework. If not, then the product will be condemned.</p> <p>Discard product that cannot be suitably reworked – inedible rendering/ landfill</p> <p>Release unaffected product</p>
<input type="checkbox"/>	<p>RECONCILIATION</p>	<p>Follow-up on controlled product DAILY.</p>
<input type="checkbox"/>	<p>DOCUMENT</p>	<p>All steps should be documented accordingly.</p>

ADDENDUM D.

An example decision tree an establishment may use to help navigate through an incident. An establishment may elect to modify this decision tree or develop its own.



ADDENDUM E.

An example scenario to demonstrate the response process.

This scenario is fictitious and for educational purposes only. An establishment may make different determinations in a similar scenario depending on the details specific to the process and incident.

Incident Description

Finding

On Monday, January 10, an employee working on the pack out line of quick-frozen ground beef patties observed something blue in a patty. The employee notified the lead and showed them the patty. QA was notified and upon examining the patty, they found what appeared to be a small piece, approximately 5 mm in largest dimension, of soft blue plastic material. QA placed the current production lot on hold because of apparent foreign material inclusion,

and emptied the system of current product being run into combo bins, pending further investigation. QA then considered that because this material did not immediately appear to be something used in the establishment, this may be a source material introduced foreign material, so QA also placed a hold on other product lots produced on the same day and the day before because of common source material lots having been used.

Investigation

Once the initial “wide net” was cast to capture all products produced with common source materials, the QA department investigated further. QA quickly found that the frozen blocks of lean raw beef trim they were bringing in from one particular supplier used box liners that appeared to be similar soft blue plastic material as found in the finished product. QA verified that trim from this same supplier was also used in the production lot in which the blue plastic was found in finished product. QA contacted the supplier to ask if they had received any complaints about their blue box liner material showing up in product at other customers, but the supplier said they had no complaints in the past year. QA then observed the process for how their company unboxes and introduces the boxed trim in liners into the process. QA observed employees opening tempered boxed

trim, grabbing the liner and allowing the partially thawed blocks of trim to essentially fall from the liner, into the top of the flaker. QA inspected several discarded liners from this process and found no missing material from those liners. Rather than stop there, the QA asked the operator of the flaker if the liners always come off easy. The operator responded that yes, usually they do, but sometimes when the product is not adequately tempered before being brought out for use, the liner can remain stuck in different places of the trim block and then the operator must stop and dig out the liner still stuck in the block before flaking it. The QA asked the operator if they had been dealing with any product that was not adequately tempered earlier in the day, and the operator didn't want to say, becoming visibly uncomfortable, and said, “yes, maybe there were a few that were hard to get out of the liners earlier today.”

Interview

QA then spoke with the pre-grind production supervisor. The QA asked them if the normal tempering process before flaking was followed with the production earlier in the day. The pre-grind supervisor explained that the lot of trim expected to be run that morning that had been tempered adequately was put on hold because of

it being part of a source material lot that was used in the production of a ground beef lot produced the previous day, which was sampled by FSIS. Because of the need to hold this source lot, production was forced to bring forward a different source material lot that had not been in the cooler long enough to temper sufficiently.

Sampling

QA statistically selected finished product cases from the held lot(s) of product using this same source material lot, and subjected the selected samples to 100% visual

inspection by thawing and breaking apart the patties to look for additional blue liner. No additional pieces of blue plastic liner were identified during the reinspection.

Questions & Answers to Consider

First, **every incident must be evaluated on its own merit**, so this is not designed to be a template to always follow where soft plastic foreign material is found in finished product, rather it is a case study of the process to follow, using critical thinking, to ensure product leaving the facility is safe, wholesome and unadulterated, and to ensure the company remains in compliance with FSIS regulatory expectations.

QUESTION 1:

Which regulatory corrective action requirement applies to this scenario, HACCP or SSOP (see note in Corrective Action section of Response)? Why? Must 418.2 notification occur?

ANSWER: Because the foreign material identified was small, and made of soft plastic, the foreign material is a contaminant, but not representative of a physical food safety hazard. Because of this, the plant determined to follow SSOP corrective actions and document, per 9 CFR 416.15(b). (In an alternate example, another establishment may have specifically included the tempering procedure in a pre-requisite program and determined to document SSOP-like correction actions for failing to meet their own procedures – that is remove the contaminated product; ensure no additional products are affected and prevent future occurrences). Because the contamination occurred within the establishment's process, notification to FSIS under 9 CFR 418.2 is not required because no adulterated or misbranded product was received by or shipped from the establishment.

QUESTION 2:

Was the action taken by the QA team sufficient to support the rest of the product and perhaps other production lots are reasonably presumed wholesome and unadulterated?

ANSWER: In this case, the QA team arguably conducted a sufficient investigation to establish the scope of impact, within reason, and supported that the situation appeared to be an isolated incident.

QUESTION 3:

Should this finding cause the company to consider additional procedures to mitigate this potential source of contamination when raw materials cannot be fully tempered before flaking? If so, what could such procedures include?

ANSWER: The investigation did uncover a vulnerability in the system that can be created by unforeseen needs to shift to different source lots of raw material. The establishment should consider whether there are mitigating procedures or practices that could be adopted to avoid this type of issue from reoccurring. What works in one establishment may not work elsewhere, so creative and applicable solutions need to be developed to fit the individual situation and company needs. (In the alternate example where the establishment considers this a failure of the tempering pre-requisite program – shifting sources of raw material and the need to ensure adequate tempering and removal of liners could be added to the pre-requisite program in effort to prevent future recurrence).

ADDENDUM F.

A list of tips and things to consider, some of which are specific to certain incidents, when responding to an incident.

- Do not rule anything out as a source only because it seems unlikely.
- When utilizing metal wire mesh belting that is believed to be metal detectable, consider running a link through your detection system with the product. Some metal belting may not be detectable in some systems, depending on the size and diameter of the links and the composition of the metal. Consider verifying each time a replacement belt or links are received.
- The location of the FM in the product can help identify the point in the process it was introduced. For example: if it is a breaded product, FM on the surface of the meat or poultry item underneath the breading suggests the FM was introduced before breading. FM within the breading suggests introduction during the breading process or through the breading mix. FM on the exterior surface of the breaded product suggest FM was introduced after breading.
- If FM is introduced early in the process, routinely using raw materials such as combos, racks, bins, etc. in the order produced for subsequent processes can help to limit the scope of the investigation and the amount of affected product implicated by the incident. For example, if a FM is found in finished product where bins of raw material were used in the order produced and no similar contamination is found outside of that finished product production time period, the scope can likely be narrowed down to a particular bins or bins raw material rather than an entire production lot or day. If raw materials are used out of order or from various sources, dates, times, etc. the scope will likely be wider.
- When selecting new chemicals be sure to understand the potential effects on various equipment and surfaces. For example, some chemicals may not be compatible with certain metals, warp certain materials, degrade plastics or other materials, or harden plastics converting them to brittle plastics.
- Ensure equipment is fit for purpose and utilized for the intended purpose. For example, a slicer designed for use with fresh product being used for frozen product or product not fully tempered may be subject to excessive wear. Incorrect application of belting materials is another common example.
- Utilize shatter proof designs or coatings on overhead bulbs to minimize the risk of damage, in addition to restraints or safety cables to ensure light fixtures stay in place.