METAL DETECTION DEVICES

MD AND X-RAYS

• Vandana Gadre

Mondelez International
SNACKING MADE RIGHT
EXTRANEOUS MATTER

Any object/material which may become part of the product being produced, which is not designed to be a part of such product.
SOURCES OF EXTRANEOUS MATTER

- **Ingredients** naturally occurring agricultural material – stems, shell, fruit pits, powder agglomerates, stones
- **Personal effects/GMP** - pens, coins, hair, pair of glasses..
- **Maintenance**
- **Equipment** - design related
- **Tools**
- **Environment**
- **Sanitation**
- **Formula** – forming hard pieces
- **Procedures and practices** - transfers
SAMPLE CONCEPT WITH (IM)PERFECT SHAPES

EXTRANEOUS MATTER CONTROL PLAN

EXTRANEOUS MATTER CONTROL PLAN

Prerequisite Programs GMP’s
- Control of Wooden Pallets
- Control of soft Plastic
- Hair coverings...

Preventive Maintenance Program
- Gasket Controls

Extraneous Matter Control Devices
- Magnets
- Sieves
- Metal Detector
- X Ray
- Other..

Glass & Brittle Plastic Program
- Inventory

Ext Matter Complaints
- Yearly basis EMCP review against complaints
- Is the plan working or what changes are required?
<table>
<thead>
<tr>
<th>VALIDATION</th>
<th>CALIBRATION</th>
<th>VERIFICATION</th>
<th>MONITORING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operational functionality</td>
<td>Technical functionality</td>
<td>Are you actually doing what you say you are going to do</td>
<td>Ensuring the system continues to detect and reject in accordance with the documented standard</td>
</tr>
<tr>
<td>Can it consistently detect and reject correct FRR and POD limits</td>
<td>Air pressure, Electrical integrity Belt tracking. Sensor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted before first production and if any issues or after maintenance</td>
<td>Conducted usually annually</td>
<td>Review and trending of results Confirm devices operational functionality</td>
<td>Ongoing at a frequency to demonstrate control - Can you hold product if something goes wrong?</td>
</tr>
</tbody>
</table>
MD and X ray Validation

Scope
Can be used for single pack, bulk products, throat or gravity fall Metal Detectors and X-Ray

Frequency
1. Prior to first production/commercialization, ideally during installation
2. Post major modification or repairs
3. Major change in the product intrinsic properties that influence the sensitivity of the device
4. Device with bad performance e.g. increased FRR

Pre-requisites
1. The equipment is set up at its optimal settings according to supplier specs & in compliance with QP test piece types and size.
2. Test piece sizes are available in 3 different sizes per type and sizes smaller than or equal to MDLZ QP and equipment specification
3. The personal performing validation should be trained; in case of external equipment supplier, also certified.
VALIDATION PROTOCOL
PART A : ESTABLISHING THE RIGHT SENSITIVITY

NOTE : Validation without product ( Design Constraints)
Same protocols with product only minimum 10% times it has to be done with product to ensure that with product or without validation results are consistent.

STEP 1 OF VALIDATION

- To start with target pieces on which the device was ordered
- Order should be within recommended sensitivity as per QP
- Pass through the device 10 times each test piece placed on / in a product / product flow
- Record each result in validation report. Yes = Detected & Rejected

STEP 2 OF VALIDATION

- If “No” is recorded on when passing the largest pieces, readjust settings and repeat Step 1.
- Ensure you are running the device on the best possible sensitivity.
- If all 10 passes are successful (= Yes), pass smaller test piece 10 times & evaluate
- Once the device is set with the smallest piece size giving 10 successful detections & rejections (= Yes), go to Second part of the validation

SETTING

Optimal settings for normal operation
Functioning Rejection device

ENSURE

Yes = Detected & Rejected
Add 20 pieces from the smallest test contaminant, evenly distributed in X quantity of foreign body free product
- Use standard line speed and product flow

Determination of X :
For bulk: Identify the finished product weight (gms or kg) in each SKU.
  Multiply FP product weight by the number of pieces packed
  (example 200–2000 pieces/kg)
For packed product: use 200 - 1000 good product
Alternative place 20 targeted contaminants in min 200 good packages / bulk product

When 20 contaminants are successfully detected and rejected, calculate the False Reject Rate and Probability of detection using "FRR and POD Report" sheet
If result does not meet 100% POD or is above 0.1% FRR readjust the settings and return to Part A Step 1
## POD & FRR Calculations

**POD (Probability of Detection)**
- **Definition:** The POD limit is defined by the smallest dimension achieving a POD of 30/30 (detected & rejected).
- **Calculation:**
  \[ \text{POD} = 100 \times \frac{\text{Rejected Test Samples}}{\text{Total Test Samples Inspected}} \]

**FRR (False Rejection Rate)**
- **Definition:** Measured during production by adding/ not adding known amount of contaminants with product amount equivalent to (200 – 2000 SKU). Evaluate each rejected product and classify it as a False Reject or not.
- **Recommended target:** not more than 0.1%
- **Calculation:**
  \[ \text{FRR} = 100 \times \frac{(\text{Total Reject} - \text{Correct Reject})}{\text{Total Inspected}} \]

**Air Interlock**
- **Definition:** In case air push is used as a reject mechanism, Validation shall include Air pressure interlock with belt / line stoppage if pressure goes beyond 4-6 bar and other failsafe interlocks.
# Filling the Format

**Metal Detector / X Ray Validation Report Part 1**

**(Evaluating Sensitivity)**

**Gravity Fall Horizontal (including bulk) Metal Detector**

<table>
<thead>
<tr>
<th>Factory</th>
<th>Manufacturing Line</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Product</th>
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<tr>
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<td>LSI validation date or state first validation</td>
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</table>

<table>
<thead>
<tr>
<th>Test piece used Metal Types</th>
<th>Reason for validation/re-validation</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Test piece sizes used</th>
<th>Speed of the line</th>
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### Table: Test Results

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</tr>
</tbody>
</table>

*Yes = Detected & Rejected  
No = Detected & Not Rejected or Not Detected & Not Rejected  
N/A = Test was not done*
WORST CASE SCENARIOS
Where is the least sensitive position in MD aperture?

<table>
<thead>
<tr>
<th>Position</th>
<th>Place check stamp here</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<tr>
<td>3</td>
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</table>
METAL POSITION IN APERTURE

Where is the least sensitive position in MD aperture?

<table>
<thead>
<tr>
<th>Position</th>
<th>Place check stamp here</th>
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<tbody>
<tr>
<td>1</td>
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<tr>
<td>2</td>
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</tbody>
</table>
1. While doing the validation test piece need to be kept as close as possible to the center of aperture.

2. Back to back contaminants.

3. Emergency Stop / Power Failure :- Such situation should be simulated to know the reaction of the detection & rejection device. (Similar For X-Ray)

4. For long packs (Leading and Trailing Edge) (Similar for X-Ray)
Worst Case scenarios considerations for X ray

For Product Packed in Jars/Glass containers

1: Top of jar (in the neck area)
2: Lay over the product
3: Top corner
4: Body
5: Bottom top
6: Bottom - corner

For Product packed in Pouches

- Horizontal Seal Top
- Side Edges
- At the Vertical Seal
- Horizontal Seal Bottom
Worst Case scenarios considerations for X ray….contd.

**Jar Inspections (Packaging variations)**

PM variations if not covered properly during the validation can lead to huge image fluctuation and in turn High FRR / Failure to detect the right contaminant.

<table>
<thead>
<tr>
<th>Bottom variation</th>
<th>Inclusion size and numbers</th>
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</thead>
<tbody>
<tr>
<td>Acceptable</td>
<td>Not acceptable</td>
</tr>
<tr>
<td>“in specification”</td>
<td>“out of specification”</td>
</tr>
<tr>
<td>Not to be rejected</td>
<td>Can be rejected</td>
</tr>
</tbody>
</table>

**Blind Spot Formation**

For tin cans or glass jars, the packaging will appear darker on X-Ray pictures than the product. Then it becomes difficult for the picture analyzer software to distinguish between the contaminant and the product and the chances are there that the X ray can miss the real contaminant.

Due to inspection geometry (focal spot position) of the X-Ray lateral view equipment, the total volume of a rigid container cannot be always inspected, as shown below on a tin can example:
**X AND Y LIMITS AND REJECTED PRODUCT HANDLING**

**X and Y**

A limit for rejections shall be defined over a defined time frame (X number of confirmed metals in Y period of time). If this limit is exceeded the rejects shall be investigated to understand cause and source.
Eg not more than 2 confirmed metal pieces in 4 hours

**Rejected Product handling**

- Reject mechanism shall divert 100% of the product into an identified bin or container to prevent re-entry into the process or product flow
- Bin shall be secured to prevent any potential metal positive material from being mixed with good products
- Product rejected shall not be directly packed without further investigation and re-evaluation
  - Rejected products and internal metal finds shall be fully investigated to determine if metal is present.
  - For rejected product during monitoring activities only - this shall be repassed through the metal detection equipment prior to further use
  - If a detection system fails to detect a test piece, the material produced since the last successful test shall be placed on hold.

**FAILSAFE CONTROLS**

Fail-safe devices which form part of metal detection/rejection systems (such as compressed air pressure used for rejection flap operation, bin full sensors etc.) shall be tested at the start of every shift. Testing shall be carried out by passing a test pack down the line while temporarily interrupting the electrical supply to the reject device solenoid (e.g., by using a key switch held by an authorized person) and observing that the reject mechanism does not operate, and that the conveyor belt then stops.