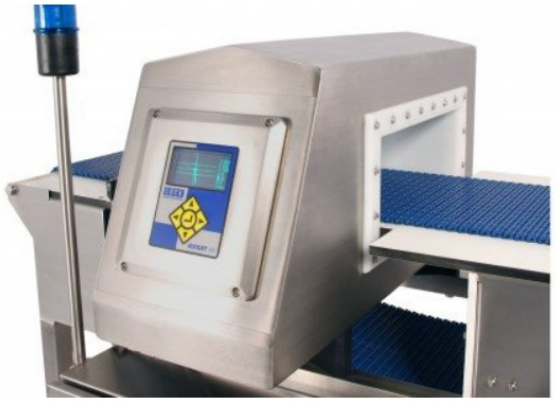
METAL DETECTION DEVISES

—

MD AND X-RAYS



- Vandana Gadre

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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.

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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

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?

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VALIDATION – VERIFICATION – MONITORING - CALIBRATION

VALIDATION	Operational functionality Can it consistently detect and reject correct FRR and POD limits	Conducted before first production and if any issues or after maintenance
CALIBRATION	Technical functionality Air pressure, Electrical integrity Belt tracking. Sensor	Conducted usually annually
VERIFICATION	Are you actually doing what you say you are going to do	Review and trending of results Confirm devices operational functionality **6mthly / yearly**
MONITORING	Ensuring the system continues to detect and reject in accordance with the documented standard	Ongoing at a frequency to demonstrate control - Can you hold product if something goes wrong?

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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 eg. 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.

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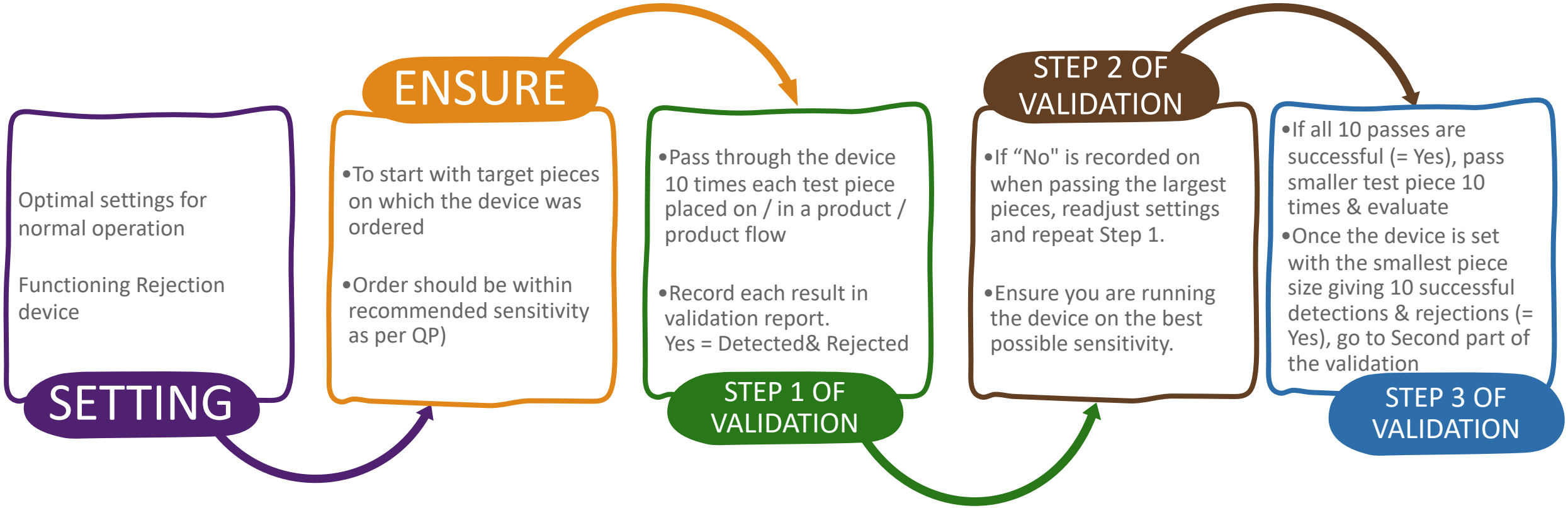
VALIDATION PROTOCOL
PART A : ESTABLISHING THE RIGHT SENSITIVITY



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

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Determining FRR & POD

Microsoft Excel Worksheet

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

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POD & FRR CALCULATIONS

POD

Pass 30 times each Validation Sample
The POD limit is defined by the smallest dimension achieving a POD of 30/30 (detected & rejected)

Calculation:- $POD = 100 \times \frac{\text{Rejected Test Samples}}{\text{Total Test Samples Inspected}}$

FRR

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:- $FRR = 100 \times \frac{\text{(Total Reject – Correct Reject)}}{\text{Total Inspected}}$

Air Interlock

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

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FILLING THE FORMAT

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Metal Detector/ X Ray VALIDATION REPORT PART 1

(EVALUATING SENSITIVITY)

GRAVITY FALL/ HORIZONTAL (including bulk) Metal Detector

Issue Date	15 May 2020 (R00)
Supersedes:	---
Chapter 5	Page 2

Factory		**Manufacturing Line**	
Product		*Last validation date or state First validation*	
Test piece used Metal Types		*Reason for validation/ re-validation*	
Test piece types/ sizes used		*Speed of the line*	

	No. Of Passes	Test piece type Stainless			Test piece type Non Ferrous			Test piece type: Glass			Test piece type		SS	Comments, if any
		1.5 mm	1,2 mm	1.00mm	2.0.mm	1.8 mm	1.6mm	____mm	____mm	____mm	2.5 mm	2.3 mm	2.1mm	
First part of Validation protoc	1	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	2	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	3	Yes	Yes	Yes	Yes	Yes	No				Yes	Yes	Yes	
	4	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	5	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	6	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	No	
	7	Yes	Yes	No	Yes	Yes	Yes				Yes	Yes	Yes	
	8	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	9	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
	10	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes	Yes	
Second part of Validation protocol	11	N/A		Yes		Yes						Yes		
	12	N/A		Yes		Yes						Yes		
	13	N/A		Yes		Yes						Yes		
	14	N/A		Yes		Yes						Yes		
	15	N/A		Yes		Yes						Yes		
	16	N/A		Yes		Yes						Yes		
	17	N/A		Yes		Yes						Yes		
	18	N/A		Yes		Yes						Yes		
	19	N/A		Yes		Yes						Yes		
	20	N/A		Yes		Yes						Yes		
	21	N/A		Yes		Yes						Yes		
	22	N/A		Yes		Yes						Yes		
	23	N/A		Yes		Yes						Yes		
	24	N/A		Yes		Yes						Yes		
	25	N/A		Yes		Yes						Yes		
	26	N/A		Yes		Yes						Yes		
	27	N/A		Yes		Yes						Yes		
	28	N/A		Yes		Yes						Yes		
	29	N/A		Yes		Yes						Yes		
	30	N/A		Yes		Yes						Yes		

Yes = Detected& Rejected

No= Detected & Not Rejected or Not Detected & Not Rejected

N/A= test was not done

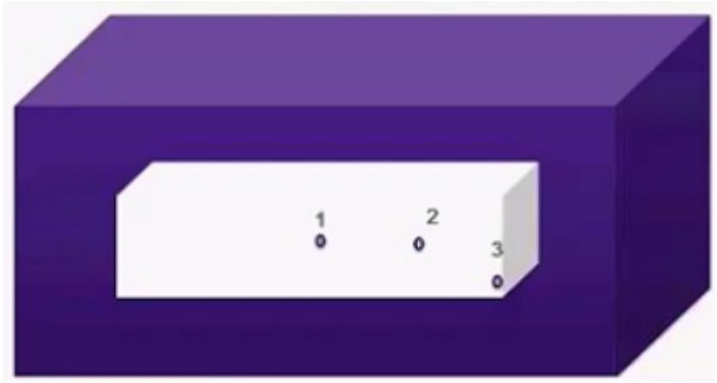
N/A= test was not done

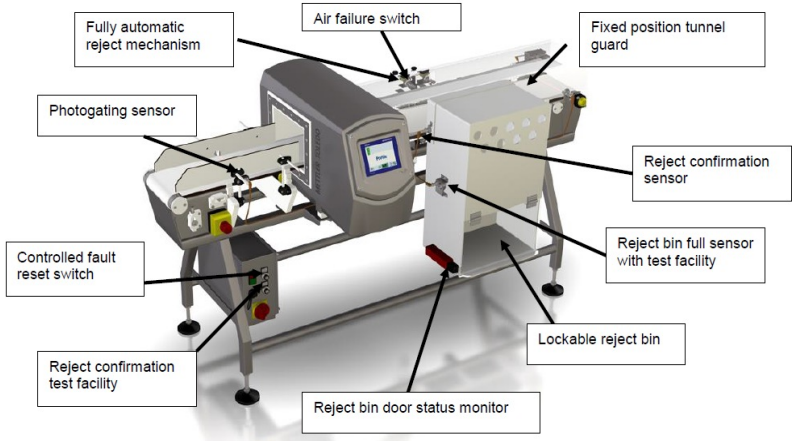
WORST CASE SCENARIOS

METAL POSITION IN APERTURE

Respond by using the green stamp to tick one of the boxes below

Where is the least sensitive position in MD aperture?

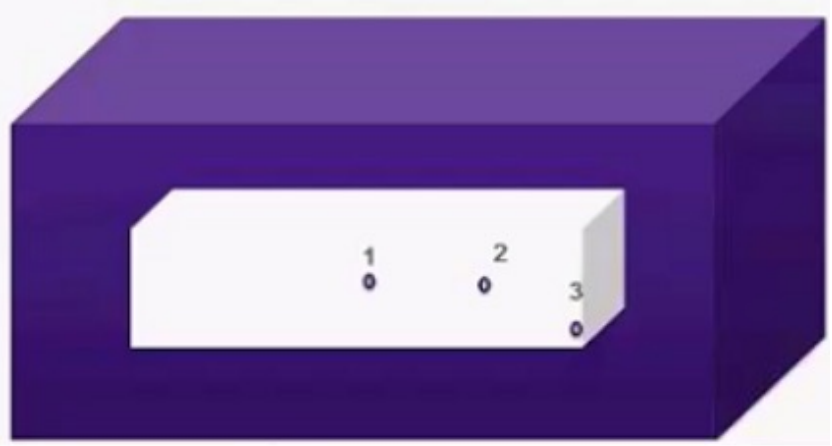


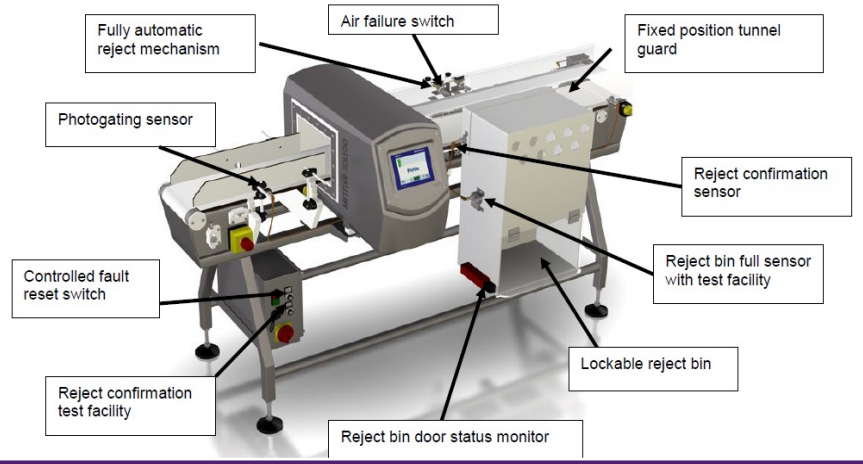


Position	Place check stamp here
1	
2	
3	

METAL POSITION IN APERTURE

Where is the least sensitive position in MD aperture?





Position	Place check stamp here
1	
2	
3	

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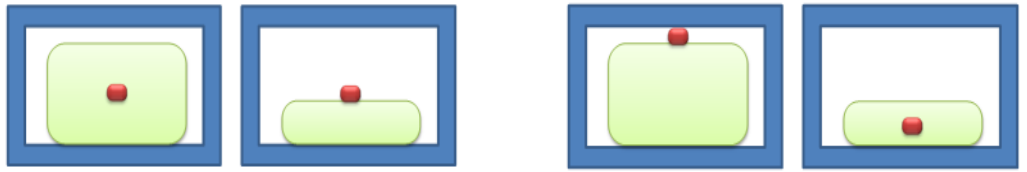
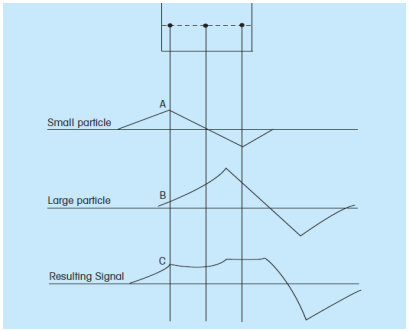
Worst Case scenarios considerations for MD

1. While doing the validation test piece need to be kept as close as possible to the center of aperture.

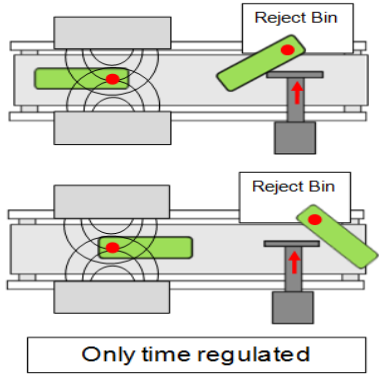


2. Back to back contaminants.

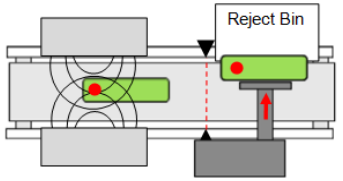


3. Emergency Stop / Power Failure :- Such situation should be simulated to know the reaction of the detection & rejection device. (Similar For X- Ray)

4. For long packs (Leading and Trailing Edge) (Similar for X- Ray)



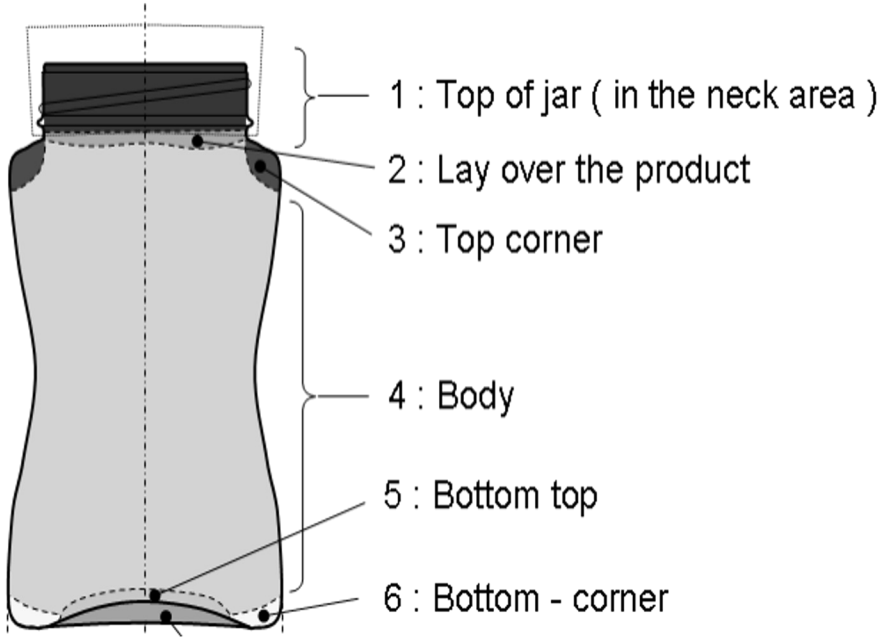
Only time regulated



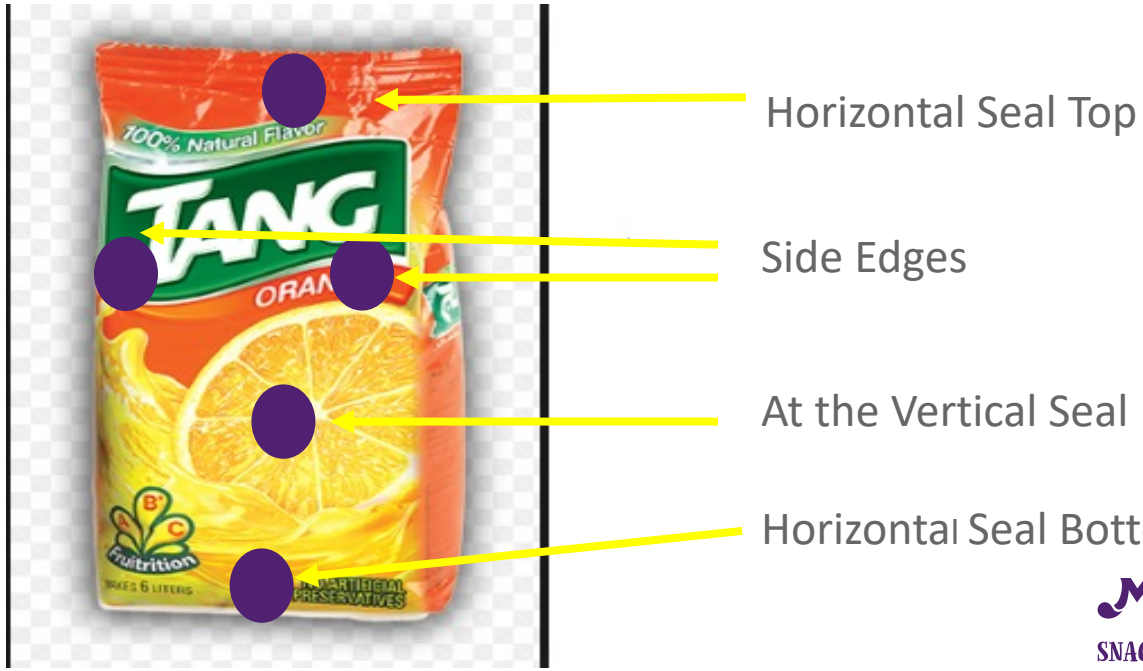
Time + Position regulated

Worst Case scenarios considerations for X ray

For Product Packed in Jars/Glass containers



For Product packed in Pouches



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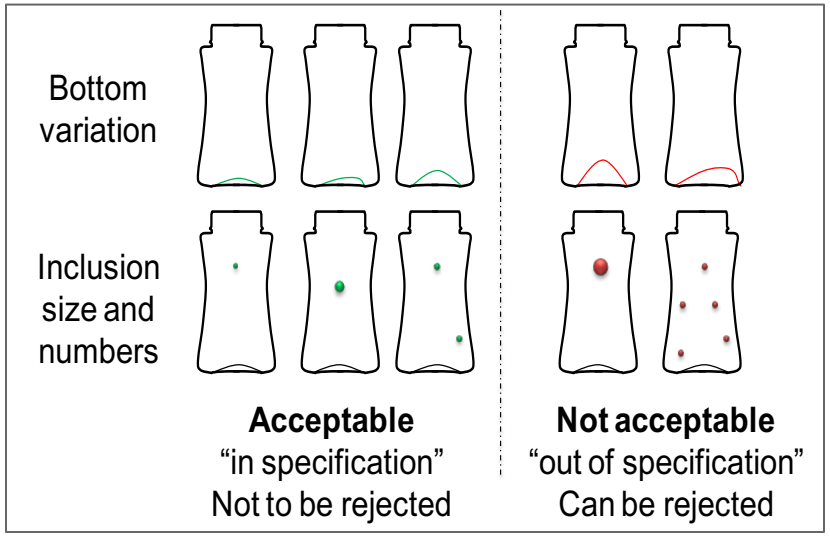
Worst Case scenarios considerations for X ray….contd.

Jar Inspections (Packaging variations)

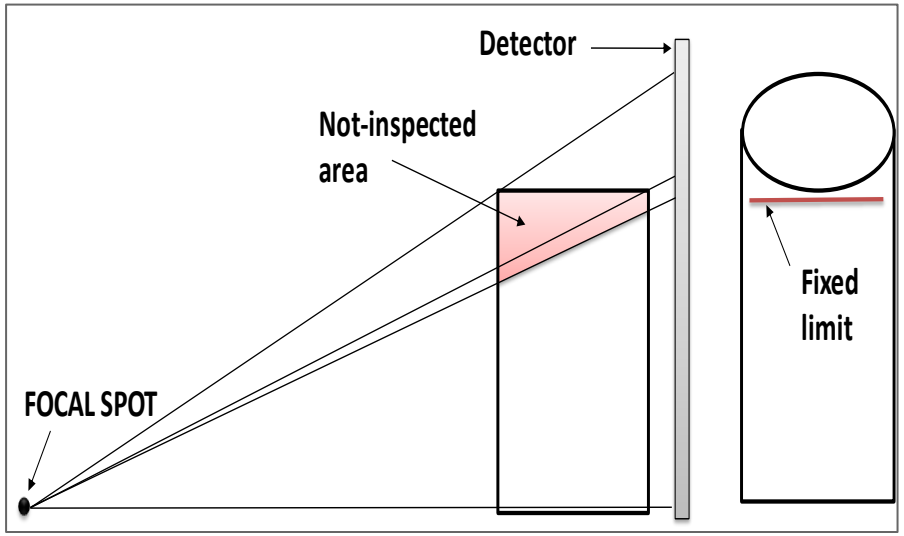
PM variations if not covered properly during the validation can lead to huge image fluctuation and in turn High FRR / Failure to detect the right contaminant.



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:



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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
  - o rejected products and internal metal finds shall be fully investigated to determine if metal is present.
  - o for rejected product during monitoring activities only - this shall be repassed through the metal detection equipment prior to further use
  - o 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.