# How to Select Critical Control Points for X-ray Systems

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Ensuring Optimal Protection Against Product Contamination

Manufacturers typically install an x-ray inspection system at the end of the production line, although it can be installed at any point during the production process. The questions are: which are the best locations for x-ray inspection? Where are the critical control points to ensure the highest levels of product safety? Should x-ray inspection be at the beginning of the production line, where the raw materials arrive, at some intermediate stage, or at the end of the line before products are shipped out? Or would product safety and quality be better served by installing x-ray systems at more than one critical control point?

These are the questions that this white paper addresses. It helps manufacturers choose the most effective locations – the critical control points – for installing x-ray inspection systems.

The paper begins by describing the capabilities of x-ray inspection systems. It then looks briefly at how x-ray inspection can help manufacturers comply with HACCP (Hazard Analysis Critical Control Points) before explaining how to select CCPs (Critical Control Points) for x-ray inspection systems.

The main part of the paper discusses the relevance of x-ray inspection to each step of the production process from raw materials to the finished packaged product. It explains why x-ray inspection might or might not be appropriate at each stage of the production process. In each case, there are real-world examples to show how cost-effectiveness and efficiency of contamination detection help determine the optimal location.

1. Why Use X-ray Inspection Systems?
X-ray inspection systems offer unsurpassed detection of physical contaminants, ensuring safety of food and pharmaceutical products. No other technology detects such a wide range of contaminants – stone, metal, glass, bone, high-density plastic and rubber, to name just a few. X-ray systems can also perform a wide range of in-line quality checks such as measuring mass, counting components, identifying missing or broken products, monitoring fill levels, inspecting seals and checking for damaged product and packaging.

Incorporating an x-ray inspection system into a company-wide product inspection program to ensure product safety and quality helps manufacturers comply with national and international regulations as well as standards set by retailers.

2. How Does an X-ray System Catch Contaminants?
An x-ray system is essentially a scanning device. When a product passes through the x-ray system a grey scale image of the product is created. The software within the x-ray system analyses the grey scale image and compares it to a predetermined acceptance standard. On the basis of the comparison, it accepts or rejects the image. In the case of a rejection, the software sends a signal to an automatic reject system which removes the product from the production line.

3. What are the Limits of Contamination Detection?
The detectability of contaminants in products using x-ray inspection is dependent on various factors such as product density and product thickness.
HACCP consists of seven steps known as principles.
1. Conduct a hazard analysis
2. Identify critical control points (CCPs)
3. Establish critical limits for each CCP
4. Establish CCP monitoring requirements
5. Establish corrective actions
6. Establish record-keeping procedures
7. Establish procedures to verify the system is working as intended

For the purpose of this white paper, we will focus on the first two principles only: conducting a hazard analysis and identifying the critical control points.

5. Conducting a Hazard Analysis

Every manufacturer should perform a hazard analysis for every product it produces to assess the risk of contaminants being present. A food or pharmaceutical safety hazard is anything that could be a threat to human health. Since x-ray inspection catches only physical contaminants, this paper deals with physical threats to human health – the fragments of stone, glass, metal, bone, or high-density plastic or rubber that could get into your product.

For the purposes of this white paper, a brief description of how to conduct a hazard analysis is sufficient.

- Create a flow diagram of the production process. Make sure you include every single operation and input – ingredients and packaging materials that touches or affects the line.
- For every process and input, identify the potential hazards. Look at the sources of the hazards as well as the actual hazards, and consider whether your manufacturing processes introduce, control or increase the hazard.
- Evaluate the likelihood of the hazard occurring. Filtering out unlikely events helps you focus on the risks that are relevant – the ones that have a reasonable chance of occurring.

Product density determines the depth of grey in the grey scale x-ray image. The denser the product, the darker the grey. To be detectable to x-ray inspection, a contaminant has to be denser than the product in which it’s embedded. That means it will absorb more x-rays than the surrounding product and show up on a grey scale x-ray image as an area that’s darker than its surroundings.

In other words - any contaminant with a density similar to, or less than that of the product in which it’s hiding is incapable of being detected by x-ray inspection. As the product thickness in the path of the x-ray beam increases, so does its overall level of absorption. This makes detection more difficult. A contaminant in a shallow layer of product on a bulk-flow production line, e.g. cereals or frozen berries, is easier to detect than a contaminant hidden inside a finished, sealed pack. In general, the smaller the product thickness the better the sensitivity of x-ray inspection.

Many other factors can affect the sensitivity of an x-ray system. The point to bear in mind is that sensitivity is not the same at every stage of a production line. Some locations are better than others for the detection of certain contaminants. (To find out more about the factors limiting the sensitivity of detection please read The X-ray Inspection Guide.*)

4. Hazard Analysis Critical and Control Points (HACCP)

HACCP was developed in the late 1960s by NASA and its partners as a way of ensuring the safety of food destined for astronauts. In 1993, the Codex Alimentarius Commission said that HACCP was the most cost-effective way to ensure food safety and it is now an international standard in the food industry.

The UN Food and Agriculture Organization defines HACCP as ‘a system that identifies, evaluates, and controls hazards which are significant for food safety’. Its a complete approach to safety, directed as much towards keeping contaminants out of the production process as it is to catching them before products leave the factory.

*More information how x-ray inspection works can be found under www.mt.com/pius-guides
Finally, think about the preventative measures you can put in place to stop or reduce the risk of these contaminants getting into the product. Concentrate on the operational procedures – frequency of maintenance, safety inspections, visual checks, encasing of the line, training etc – that will keep physical contaminants out. Bear in mind that some hazards may require more than one preventative measure.

A hazard analysis requires that all hazards which may be reasonably expected to occur (including hazards that may be associated with the type of process and facilities used) are identified and assessed. The potential sources of contamination also need to be identified. For example, if a producer makes snack/cereal bars, the hazard analysis may show a potential risk of contamination from the following areas:

- Stone and glass – from incoming raw materials
- Sieve wire – from damaged sieves
- Blades or paddles – from mixing and blending of ingredients
- Metal fragments – from the rolling process
- Cutting blades – from final cutting of the bars

These are just a few simple examples; they show that different types of foreign bodies can cause potential contamination at different stages of the process.

X-ray inspection is a popular control for areas where physical contamination hazards are identified. Once a critical control point is identified, x-ray inspection should be incorporated into the HACCP plan.

6. Identifying Critical Control Points (CCPs)

When all of those controls are in place, you have a safe production line – but not a foolproof one. No matter how rigorous you are, some contaminants will creep through and some processes can introduce new contaminants. Also, depending on the quality of your suppliers, your raw ingredients could already be contaminated when the products arrive at your production site.

This is the stage where you need to think about additional control measures such as x-ray inspection. The question is: where should those systems be placed on the production line?

The second stage of HACCP – identification of CCPs – helps you to choose the best place to install an x-ray system. A CCP is a step or process that’s essential to product safety – it’s the point at which control must be applied to reduce the risk of contamination to acceptable levels.

The traditional method of determining CCPs is to work through a decision tree, usually the one recommended in the Codex Alimentarius. Although the methodology is rigorous, it’s not always the most appropriate for capital investment items such as an x-ray inspection system. Other factors such as cost effectiveness, and practicality are just as likely to influence the decision on whether to order an x-ray inspection system, and where to place it. The reality of manufacturing is that a risk based balance should be established which considers costs and complexity against total risk elimination.

Let’s side-step the decision tree and look at where x-ray inspection will be most effective at catching contaminants on the production line:

1. Raw ingredients
2. Bulk-flow (Loose) products
3. Pumped products
4. Before and during processing
5. After processing
6. Before packaging and sealing
7. After packaging and sealing
8. Final cases

6.1 Raw Ingredients

Raw ingredients come with a high risk of contamination. Manufacturers are reliant on the quality control standards of their suppliers. Some manufacturers even insist that their suppliers have x-ray inspection systems installed in order to reduce the risk of contaminated raw ingredients.

Eliminating the risk of contaminants as early as possible in the production process can be vital. An undetected stone or piece of metal can cause damage to the downstream processing equipment, or it could be made smaller, making detection more difficult. Early detection keeps costs down by eliminating contaminants before adding value to the product.
**Example - First stage of production:** A cereal manufacturer inspects all incoming ingredients using a bulk-flow x-ray system to eliminate the risk of contaminated ingredients. The early detection saves the manufacturer money as the contaminated product is rejected from the line before being processed and packaged, minimizing his product waste.

### 6.2 Bulk-flow (Loose) Products

Typical bulk-flow applications include raw ingredients like grains and fruits. Other typical products could be peanuts, extruded snacks, dried fruits, vegetables, sweets and pulses.

Bulk-flow products are presented in a layer at a constant depth on a conveyor, typically 25mm or less. This small depth offers outstanding levels of sensitivity for x-ray inspection – up to four times more sensitive than inspecting finished packs. That’s why it’s worth thinking about placing an x-ray inspection system early in the process where it can inspect incoming goods or raw materials. Contaminants can be removed at the source and immediately traced back to the supplier.

**Example - Shallow product is easier to inspect:** A processor of frozen berries chose to inspect its products on a bulk-flow x-ray system. Sensitivity and contaminant detection rates were much higher in a 25mm depth of bulk-flow products than in the 10kg bags in which the berries were packaged.

### 6.3 Pumped Products

Pumped products are typically slurries, semi-solids, and fluids before final packaging and addition of further value to the product. Typical applications include sauces, jams, minced meat, whole muscle, chocolate, fruit purée, dairy spreads and pharmaceutical slurries.

Like bulk machines, an x-ray pipeline system is usually located upstream to inspect products at an early stage. It offers very good detection levels because the product is homogeneous and usually pumped through an inspection manifold that is 50mm deep or less. It is much easier to find a contaminant in a pipeline system than in finished products such as glass jars.

**Example - Inspection of pumped ground meat:** A ground meat processor inspects its products using a pipeline x-ray system before packaging it in plastic trays. This offers improved sensitivity as the product is homogeneous and saves costs as product waste is minimized.

### 6.4 Before and During Processing

Processing changes the nature of the product, often making it more difficult to find contaminants. Cooking can produce chemical changes that alter the density of physical contaminants, while mechanical processing breaks them up into smaller pieces.

- The density of cooked bones is much lower than that of uncooked bones. When bones are cooked the collagen in them breaks down thereby weakening the bonds that holds the calcium together in the bones, which makes the bones harder to detect. The change is most pronounced in poultry bones.
- Physical contaminants could also damage processing equipment leading to downtime, costly repairs and additional metallic contaminants from damaged machinery.
- Processing can break contaminants down into smaller particles that are harder to catch and more widely spread. Typical x-ray systems used before or during the food processing are bulk-flow and pipeline x-ray systems, but there is also a range of conveyorised x-ray systems available to inspect products such as raw chicken breasts.

**Example - Minimum contaminant size:** The minimum size of physical contaminants that must be detectable depends upon the product. The standard for baby food, for example, is typically much higher than for pet food. Catching larger glass contaminants before processing makes detection easier and stops them being broken up into small pieces, which may not be detectable at a later stage in the production process.

### 6.5 After Processing

Food processing can be a source of fresh contamination. Worn or damaged equipment can shed shards of metal, while undiscovered contaminants can cause equipment damage that can introduce further physical contaminants into the production stream.
It’s possible to leave x-ray inspection to the end of the production line. After all, that’s the place to intercept any contaminants that have not been caught elsewhere. But at each step of the production process, there’s a chance that existing contaminants will cause more damage and be broken down into even smaller pieces.

Examples - Inspection of pumped jam: A jam manufacturer used a pipeline x-ray system to inspect the final cooked and mixed fruit jams before being filled into glass jars. Pumping the jam through a pipeline system presents it in a homogenous layer in which detection of contaminants is easier. This also minimizes product waste as the jam has not yet been filled into containers.

Removing contaminants in jellies: A confectionery manufacturer installed a bulk-flow x-ray system on its jelly sweets production line. The system is situated at the end of the line, before the jellies are packaged into bags. The x-ray system detects different contaminants and has even detected tiny pieces of plastic from the jelly moulds.

6.6 Before Packaging and Sealing

The closer you get to the end of the line, the more likely it is that manufacturers will choose to place their x-ray inspection equipment at the very end. That’s when x-ray inspection becomes a catch-all for any contaminants that haven’t been removed elsewhere in the line. But there are arguments for moving the unit upstream.

- X-ray inspection is more effective at detecting contaminants in products which haven’t been packaged or when the final package hasn’t been sealed.
- It’s more costly to reject portioned and packaged product than it is to reject product that’s still being processed.
- There may not be enough space at the end of the line for an x-ray inspection system.

Example - The line is fully enclosed: A manufacturer of tinned ready meals decided to inspect the tin content just after they poured in tomato sauce, but before they put on the lids. Because the line was fully enclosed, they reasoned that the chance of anything getting into the tins between x-ray inspection and lid application was negligible.

6.7 After Packaging and Sealing

This is the most common line location for x-ray inspection systems. Since packaging comes in so many formats – glass jars, metal cans, glass and plastic bottles, bags, trays, containers, pouches etc. – equipment manufacturers have developed a wide range of x-ray inspection systems to suit each application.

The product sealing process can itself introduce contamination. For example the screwing of lids to glass jars can cause shards of glass to break off and fall into the product. By installing an x-ray system at the end of the production line, the sealed product can be inspected and contaminated products can be removed from the production line before being packaged and shipped.

Another benefit of installing x-ray inspection systems at the end of the production line is that manufacturers can incorporate additional quality-control checks such as:

- Checking the over and underfill of products such as yogurt pots
- Counting components, for example pralines in a chocolate box
- Measuring gross and zoned mass of a tray of pork, pies or cakes
- Detecting broken, misshapen, or misaligned products like tablets in a blister pack
- Checking for the presence of inserts like instruction leaflets in blister packs or giveaways in cereal boxes
- Detection of damaged packaging; such as dented metal cans
- Inspecting tray seals for trapped product or contaminants that might compromise the sterility and freshness of the product

All of these checks can only be performed at the end of the production line. (To find out more about these extra topics please download the white paper X-ray More Than Just Contamination Detection - www.mt.com/xrayus-integrity.)

Examples - Checking a chocolate box: A manufacturer of chocolates wanted to perform several checks at once – to find contaminants, to check the alignment of the chocolate in the box, and to inspect the airtight seals for stray product. Only x-ray inspection could do this.
**Example - Packaging integrity of blister packs:** A blister pack manufacturer installed an x-ray system at one of their over-the-counter blister packaging lines, which had a problem with broken tablets and occasionally crushed or folded blister packs inside the packaging. The x-ray system detects and rejects contaminated products, but also verifies product and packaging integrity.

**6.8 Final Cases**

X-ray inspection is a powerful tool. A large x-ray inspection system can detect contaminants inside cases as large as 500mm wide by 450mm high. Typical examples may be single or multiple primary small packs inside a larger secondary pack/case or loose products in large bags/sacks before being shipped.

**Examples - Checking for glass in pet food:** A pet food manufacturer is using an x-ray system at the end of the production line to inspect large cases, each filled with primary packs of pet food, as there was no room for an x-ray system at an earlier stage on the production line. Sensitivity levels were lower than they would have been on single retail primary packs, but they were content to detect glass shards 5mm and larger.

**Zoning for crisp packets:** A manufacturer of crisps uses two x-ray systems to inspect cases, each containing 12 bags of crisps. They look for physical contaminants (metal from processing, glass and stone from the potato fields) and flavoring lumps. By analysing the saved x-ray reject images, the customer could identify which individual chip bags inside each case were faulty.

**7. Conclusion**

The first step to locating an x-ray inspection system on a production line is the HACCP process and the determination of CCPs. Without that crucial background information, x-ray inspection will not be grounded in the overall HACCP approach, and product safety could be compromised.

That knowledge has to be set in the context of x-ray inspection technology and an understanding that equipment sensitivity is not the same at every stage on a production line. Detection levels are typically better in the early stages of the production process where unprocessed product can be presented in a smaller depth and with a more uniform texture. As the line progresses, the nature of contaminants can change too. Each processing step can introduce new contaminants, or break existing contaminants down into smaller, less detectable pieces.

Catching contaminants early is not just more efficient in terms of reduced costs and waste, it also helps prevent damage to processing equipment, which in turn can introduce more contaminants. Even so, contaminants can be introduced at any point on the production line.

Installing x-ray equipment at the end is the safest way of detecting contaminants in a single operation. Since the production process is over and the product is sealed, no further contaminants can enter the product. The end of the line is also the point where manufacturers can use x-ray technology to catch other quality control issues.

The final decision usually comes down to establishing a balance between risk and cost. While few manufacturers install more than one x-ray inspection system on a single line, most choose just one, and they install it where they get optimal results. They choose the location based on their analysis of detection levels, risk levels, potential for equipment damage and downtime, brand reputation and cost of waste. In short, they make a business decision. However, as highlighted in this white paper, there are occasions where it would be necessary to install more than just one x-ray system on the production line and that's why there is no single solution that's right for every production line. Each manufacturer has to analyse its own production process to define its own CCPs. CCPs and product safety are the keys to choosing what kind of x-ray inspection system to install, and where to install it.

**Sources**

1. Food and Agricultural Organization Guidelines for the application of the hazard analysis critical control point (HACCP) system, Rome, Food and Agricultural Organization, 1993 (Codex Alimentarius Commission.)
Further Information about X-ray Inspection

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