The X-ray Inspection Guide

Building an Effective Program

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Contents

Introduction

If you're a food or pharmaceutical manufacturer, you're responsible for the safety of your products. X-ray inspection systems are widely used in the food and pharmaceutical industries to ensure product safety and quality, and this guide provides a single and definitive source of reference to x-ray inspection technology for use in those industries. It covers all aspects of the subject, starting with the basic principles – all the way through to implementing a comprehensive x-ray inspection program.

Chapters 1 to 9 cover how x-ray systems work and how you should select an x-ray inspection system:

- The Science of X-ray Inspection – explains what x-rays are and how can they be used to inspect products?
- Safety of Food X-ray Inspection – explains how to create a safe operating environment for personnel working in a location where x-ray systems are present.
- Metal Detection, X-ray Inspection or Both Technologies? – A guide to choosing either or both types of inspection processes.
- Choosing the Right X-ray System for Your Application – discusses x-ray system options and selecting the appropriate type to match your precise demands.
- Key Design Features of an X-ray System – describes what it does, and how it works to obtain the best results.
- Key Factors Affecting Sensitivity – one of the most crucial aspects of x-ray inspection, explored and explained.
- Selecting the Right Diode Size for Your Product – a crucially important technical choice for ensuring optimum x-ray functionality.
- X-ray Inspection is More Than Just Contamination Detection – explains what you need to know about the full capabilities of x-ray inspection.
- Choosing a Complete X-ray Solution – making the right choices when building a comprehensive x-ray system.

Chapters 10 to 21 cover how you can build an effective x-ray inspection program:

- Reasons for an x-ray Inspection Program – putting x-rays in the context of your entire product safety management operation.
- Building an Effective x-ray Inspection Program – explains how to create a comprehensive strategy that ensures brand, product and customer protection.
- Prevention of Foreign Body Contamination – provides a guide to minimizing and eliminating contamination before and during the production process.
- Selecting the Right Critical Control Points – describes where to place x-ray inspection systems on the production line so as to achieve optimum results.
- Operating Sensitivity – discusses ways of fine-tuning x-ray systems to ensure proper operating functionality in accordance with production-line conditions.
- Installation, Commissioning and Training – offering a comprehensive guide to pre-operation processes for x-ray inspection machinery.
- Performance Verification and Auditing – outlines procedures for collating and analyzing data for a true picture of x-ray inspection effectiveness.
- Dealing with Suspect and Rejected Product – learning from the occurrence of rejected product in order to minimize future contamination issues.
- Total Cost of Ownership (TCO) – explains how to work out cost, investment and revenue issues of x-ray system acquisition.
- How to Prove Due Diligence – ensuring that you have the data and paperwork to demonstrate your due diligence thoroughness and attention to detail.
- Data Analysis and Program Improvement – describes how to enhance your operational success and effectiveness.
- Connectivity Solutions – provides an essential guide to all the issues raised by this fundamental system process.

Brand reputation – a precious asset that must be protected

Brand reputation is a precious asset that can take years to build, so it needs to be protected at all costs. Brand reputation is also fragile and vulnerable, and it can be easily injured by customer complaints, safety scares and product recalls. A single shard of glass or sliver of metal found in a product purchased by a consumer is enough to severely damage a hard-won reputation that has been built up over a long period of time. It is clear, therefore, that the impact of product contamination can be huge and extremely negative, which is why food and pharmaceutical manufacturers increasingly use x-ray inspection systems to detect physical contaminants. Using an x-ray system as part of a product inspection program protects consumers, avoids product recalls, safeguards brand reputations, and secures revenue.

X-ray inspection – detects contaminants and performs in-line checks:

X-ray inspection technology is highly effective at detecting ferrous and non-ferrous metals, as well as stainless steel, even when products are packaged in aluminum foil or metalized film. X-ray technology can also detect glass, mineral stone, calcified bone, and high-density plastics and rubbers.

In addition to identifying contaminants, x-ray systems can simultaneously perform a wide range of extremely valuable in-line quality checks, including:

- Measuring zoned and gross mass.
- Measuring length.
- Counting components.
- Identifying missing or broken products.
- Monitoring fill levels.
- Inspecting seal integrity.
- Checking for damaged packaging.
- Detecting agglomerates such as flavor and powder lumps.
- Measuring head space.

However, while x-ray inspection can identify contaminants and perform in-line quality checks, it can't guarantee on its own, that a product's in a suitable condition for sale or that it's free from contaminants. That's why x-ray inspection must form part of a company-wide product inspection program.

Food manufacturers – subject to extensive international guidelines

Food manufacturers are under increasing pressure to adopt the standards of the Global Food Safety Initiative (GFSI). Other directives and standards, such as HACCP (Hazard Analysis and Critical Control Points) and GMP (Good Manufacturing Practice), are important and are designed to help food and pharmaceutical manufacturers make their processes as safe and transparent as possible.

HACCP is a systematic and preventive approach to food safety from biological, chemical, and physical hazards (in production processes) that can cause the finished product to be unsafe. HACCP recommends measurements to reduce these risks to a safe level – which is why it is referred to as prevention of hazards rather than finished product inspection. The HACCP system can be used at all stages of food production, and preparation, including packaging and distribution.

Implementation of a product inspection program that incorporates x-ray inspection helps manufacturers to achieve compliance with HACCP (see Table 1) and its supporting standards. These include:

- BRC (British Retail Consortium) Global Standards, a leading global safety and certification program.
- IFS (International Featured Standards), which audit branded food product manufacturers and suppliers.
- FSSC22000 (Food Safety System Certification) – a standard based on ISO 22000 (International Organization for Standardization) which sets out the requirements for food safety management systems.
- SQF Standards (Safe Quality Food) – initiated by the Safety Quality Food Institute in the US, this is an assurance code for the food manufacturing and distribution industries.

As well as helping manufacturers to conform to national and international regulations, x-ray inspection can also help manufacturers conform to retailers' Quality Control (QC) requirements.

Legislation and Guidelines	**HACCP by CODEX Alimentarius (WHO & FAO)** The Codex Alimentarius Commission was established by the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) in 1963 to develop harmonized international food standards, guidelines and codes of practice to protect consumers' health and ensure fair practice in the food trade	
Supporting Standards	HACCP implementation standards: BRC; IFS, FSSC22000, SQF	Hygienic equipment standards: EHEDG, NSF, 3A
Manufacturers' Requirements	Contamination control equipment and documentation, as well as trained operators	Hygienically-designed equipment

Table 1

Introduction

Hazard analysis – the foundation for effective inspection programs

Hazard analysis should be the starting point for an effective x-ray inspection program. Hazard analysis is also the first of The Seven Principles of HACCP (see Table 2).

This guide helps manufacturers to implement an x-ray-based product inspection program that adheres to the Seven Principles of HACCP. The use of x-ray inspection is crucial to achieving successful HACCP results, since it is the mechanism whereby contaminants can be identified and physically removed, thus making the most important contribution to the entire product safety process.

The Seven Principles of HACCP	Key Reference Sections and Chapters
1. Conduct a food safety hazard analysis	Section 13.1
2. Identify the Critical Control Points (CCP)	Section 13.2
3. Establish critical limits for each CCP	Sections 13.3 / 14.3
4. Establish CCP monitoring requirements	Section 13.4 / Chapter 16
5. Establish corrective actions	Section 13.5 / Chapter 17.3
6. Establish record-keeping procedures	Section 16.5
7. Establish procedures to verify that the system is working as intended	Chapter 16

Table 2

As well as being applicable to food, HACCP is increasingly being applied to other industries, such as cosmetics and pharmaceuticals.

In addition, pharmaceutical manufacturers can comply with industry-specific local regulations and legislation, and with GMP (Good Manufacturing Practice, see Table 3), which is a set of internationally-recognized guidelines for the manufacture of drugs and medical devices. They can conform to these standards by implementing a product inspection program which uses x-ray systems.

Legislation and Guidelines	GMP (Good Manufacturing Practice)	
Supporting Standards	21 CFR (Code of Federal Regulations) Part 210 21 CFR Part 211	21 CFR Part 11
Manufacturers' Requirements	• Documentation that proves operators are trained. • Proof that equipment is tested, calibrated and that it is not additive or absorptive to product.	• Equipment has electronic records and signatures produced in accordance with required standards.

Table 3

Pharmaceutical regulators and the pharmaceutical industry have adopted the WHO version of GMP in more than 100 countries, primarily in the developing world. GMP helps to ensure drug quality by imposing several key disciplines, including the correctness and legibility of documentation relating to manufacturing and control. For example, data transfers must be performed in specific ways in order to avoid mistakes (when writing down a balance reading).

After the first person has written down a balance reading, a second person is then required to check the accuracy of the recorded reading.

In the event of a legal claim, a product inspection program can help to demonstrate that all reasonable precautions were taken throughout the manufacturing process.

Notes

The Science of X-ray Inspection

To make an informed decision about x-ray inspection systems, it's important to understand the science and technology that lie behind x-rays. This chapter briefly covers the history and science of x-rays, before describing the main components and operating principles of an x-ray inspection system. The chapter also provides an introduction to x-ray generation and absorption.

1 The Science of X-ray Inspection

1.1 A Brief History of X-ray Discovery

On November 8th, 1895, German physics Professor Wilhelm Conrad Röntgen stumbled upon x-rays while experimenting with cathode rays (the name then given to electron beams) in a glass tube. The x-rays accidentally leaked through the glass and into a nearby cardboard box, where they made fluorescent material-coated paper glow. Röntgen didn't know what these rays were, so he called them 'x-rays' ('X' being the name typically given to unknown quantities in mathematical problems).

Röntgen wrote an initial report 'On a New Kind of Ray: A Preliminary Communication', and on December 28th, 1895 submitted it to the Würzburg's Physical-Medical Society journal. This was the first paper written on x-rays, and having referred to the radiation as 'X', to indicate that it was an unknown type of radiation, Röntgen continued to call them by that name, although (despite Röntgen's great objections), many of his colleagues suggested calling them 'Röntgen rays'. They are still referred to as 'x-rays' in many languages, including German. In 1901 Röntgen received the first Nobel Prize in Physics for his discovery.

1.2 What are X-rays?

X-rays are a form of powerful light. They occur as higher-energy electromagnetic radiation that travels at the speed of light, and in straight lines – just like regular light waves do. However, their wavelength (the distance between one wave crest and the next) is thousands of times shorter than the wavelengths of ordinary light, so the frequency with which x-rays occur is much greater. As the energy of electromagnetic waves is directly related to their frequency, x-rays are much more energetic and penetrating than light waves – which allow x-rays to travel through materials that ordinary light waves can't penetrate.

Some materials (such as glass and plastic) let light pass through them very easily, while other materials (such as wood and metal) don't allow light through as easily. When x-rays enter a material, they have to move through a large number of atoms in order to emerge from the other side – and it's the electrons in those atoms that form the main barrier to x-rays. The more electrons there are, the more chance they have of absorbing the x-rays – and so the less likely the x-rays are to emerge from the material.

X-rays tend to pass through materials made from lighter atoms with relatively few electrons, but they're stopped by heavier atoms which contain more electrons. Lead, a heavy metal with 82 electrons, is particularly good at stopping x-rays, which is why x-ray technicians in hospitals wear lead aprons and stand behind lead screens.

The fact that some materials let x-rays travel through them more easily than others is at the heart of x-ray inspection. For example, when x-ray images are taken of packaged goods on a production line as part of the product inspection process, dense contaminants (containing a high level of atoms and electrons) such as shards of metal, calcified bone, mineral stone or other such materials, will absorb more x-rays relative to their surrounding materials ('relative absorption'), and so the contaminant will show up on the x-ray and will be easily identified by an x-ray inspection system.

1.3 Modern Uses for X-rays

These days, x-ray systems are specialized, highly efficient and exceptionally advanced. They are now in common use for many types of inspection processes.

Medical Applications

The medical world uses short-exposure x-ray systems, so that the patient is only exposed to x-rays for a limited time, in order to remain well within safe limits. Short-exposure x-rays also ensure that a sharp image is created (like a quick photo snapshot), since even a slight movement by the patient being x-rayed will blur the image.

Construction Applications

In the construction and manufacturing industries, x-ray inspection checks are used to inspect internal components for material defects, cracks and weaknesses. This type of x-ray inspection involves stationary applications and short exposure times.

Security Applications

Most people come across security-based x-ray systems in the form of baggage x-ray inspection at airports. Other typical applications include use by various authorities in locations such as post rooms and for security at large public events. Modern security inspection systems offer advanced techniques, such as being able to discriminate between different materials, but they usually only look for large objects. These kinds of x-ray systems often have low resolution and rely on operator skills for full interpretation of the screen image.

Food and Pharmaceutical Applications

X-ray systems for the food and pharmaceutical sectors are built to work in tough working environments. They are fully automatic, run at high line speeds and are commonly designed to find a range of contaminants – usually of a very small size. Including x-ray machines within an effective overall product inspection program offers manufacturers brand protection, minimizes risk to consumers and greatly reduces the possibility of costly product recalls.

This guide concentrates on x-ray applications in the food and pharmaceutical industries.

1.4 Principles of Modern X-ray Machines

Like other types of x-ray machine, those used in food and pharmaceutical industries produce their own x-rays within the body of the machine. These are generated in a tube consisting of a glass envelope (see Figure 1.1), a filament cathode, a copper anode and a tungsten target. The cathode (point A) is the source of electrons, and it comprises a tungsten filament heated to incandescence (where heat is so great that it is converted into light) by an electric current.

Electrons are accelerated to the target (point B) by applying a high voltage (kV) between the anode (point C) and the cathode. The electron flow at this point is known as the 'tube current' expressed in milliamps (mA).

When the electrons hit the tungsten target mounted inside the copper anode, they decelerate rapidly. The deceleration creates the x-ray emissions.

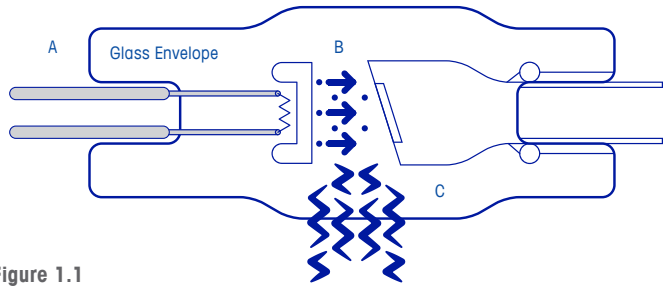

Figure 1.1

The tube is shielded in an x-ray generator by copper, and the assembly is mounted inside a copper-lined casing filled with oil, which acts as a cooling and electrically isolating medium. The useful x-ray beam leaves through a small window in this tank. Figure 1.2 shows a 'monoblock' tank design, which is usually made from a single piece of material, rather than several components.

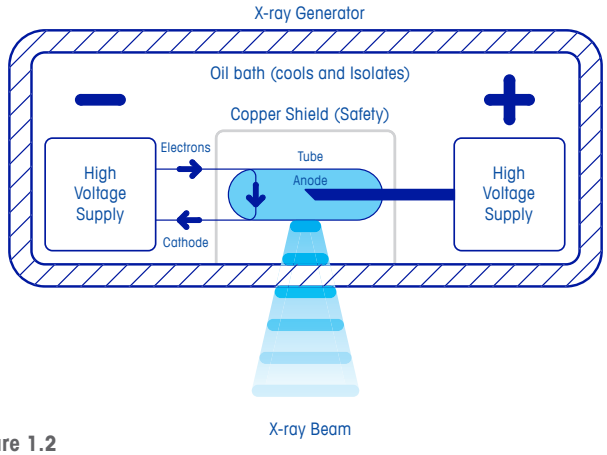

Figure 1.2

Depending on the voltage and current, x-ray production generates heat which must be dissipated. In a monoblock tank (typically 20W to 100W), the oil bath helps to conduct the heat away from the tube. External cooling fins dissipate the heat because the ambient atmosphere around the generator is usually low enough, by comparison, to do so. Larger generators (400W and above) may require a pumped system to circulate the oil through a closed loop and a radiator which, again, uses air as the cooling medium.

1.5 What are the Components of an X-ray System?

As Figure 1.3 shows, there are three key components of an x-ray inspection system:

- X-ray generator (A)
- Detector (B)
- Control System (C)

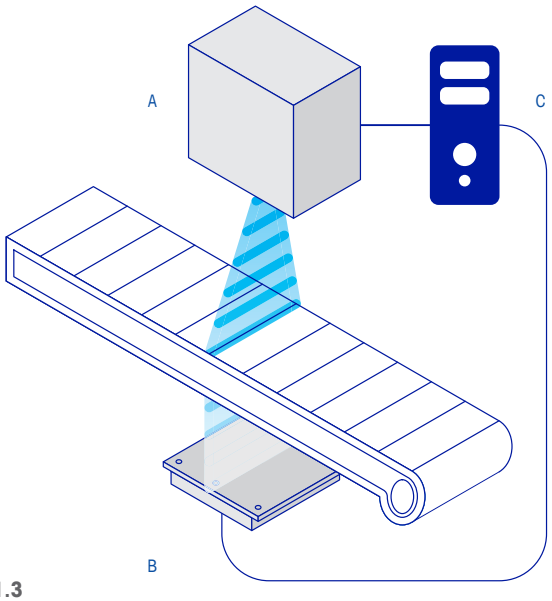

Figure 1.3

A. X-ray generator

In food and pharmaceutical x-ray systems, x-rays are funneled through a 'collimator', which is a mechanical device that narrows the beam of x-rays. The collimator is placed at the exit window of the x-ray generator. Only those x-rays traveling in a specific direction can pass through the collimator. X-ray systems incorporate collimators because it's not possible to focus short-wavelength radiation using lenses.

Since the x-ray generator is typically mounted in the top of the cabinet, the x-ray beam passes downwards, via the collimator, through the product to be examined and the belt on which the product travels.

B. Detector

The x-ray beam then strikes the detector beneath. The beam is about 2mm wide in the direction of conveyor travel, and triangular in shape. From a small point at the x-ray source, the beam diverges outwards through the collimator to its widest point across the width of the conveyor on the belt surface and the underlying detector.

The x-ray detection surface is made from a 'scintillating' material that can turn x-rays into visible light. The scintillating surface lies beneath a narrow window in the upper face of the x-ray cabinet. Both the window and the scintillating material reach across the width of the belt.

The more x-rays that hit the scintillator, the brighter it glows. This is because the output of the scintillator is proportional to the quantity of radiation striking it. Underneath the scintillator strip is a row of photosensitive diodes*. These are diodes that are sensitive to light, which means as light increases, the diode resistance drops – and as light decreases, resistance rises. A common commercial use for photosensitive diodes is to automatically turn on street lights and garden lights when it gets dark.

*A diode can be defined as a two-terminal electronic component with low resistance to current in one direction, and high resistance in the other. Its most common function is to allow an electric current to pass in one direction, while blocking current in the opposite direction.

Regular x-ray systems contain one detector, which consists of individual diodes that convert the level of detected x-ray dose into an electrical signal. This signal is scanned by the system's electronics and a 'line' of data, representing each diode in turn, is passed to the on-board Control System.

The diodes are equally 'pitched' or 'tuned' so that they all act in the same way, forming an array within the detector. Various diode pitches are available; standard pitches are 0.4mm, 0.8mm and 1.5mm (diodes are discussed in more detail in Chapter 7).

C. Control System

The diodes, which are optically coupled to the scintillator, convert the level of visible light into an electrical signal, which is sent back to the machine's on-board Control System. The Control System compiles a 'gray-scale' x-ray image (i.e. a monochrome image in shades of gray, black and white) of the inspected product, which is then analyzed by the manufacturer's proprietary Control System software. The software accepts or rejects the image (and the pack it represents), based on a predetermined acceptance standard. For rejected x-ray images, it sends a signal to an automatic reject system, and the faulty pack is rejected from the production line.

The x-ray generator, detector and Control System are at the heart of every x-ray system, and together, their design and performance influence the machine's capabilities. Many x-ray machine models are available, incorporating various hardware configurations (discussed in greater detail in Chapter 4). In modern factories, the ability to carry out multiple inspection routines on a single system is a huge benefit, and this capability is determined by the system software (discussed in Chapter 8).

1.6 X-ray is all About Absorption Difference

The amount of x-ray energy absorbed during an x-ray beam's passage through a product is determined by product thickness, product density and its atomic mass number. The absorption is known as the 'linear attenuation coefficient'. When a pack or product passes through the x-ray beam, the beams are absorbed by the pack or product, with only the residual energy reaching the detector. Measurement of the differences in x-ray beam absorption between product and contaminant is the basis of x-ray inspection.

Usually, food products contain compounds made from elements with an atomic mass of 16 and under – mainly H (hydrogen), C (carbon), and O (oxygen). The absorption of x-rays by food products containing low-mass elements is proportional to their density and thickness. In other words, the thicker or more dense the product, the more x-rays it absorbs.

A potential contaminant becomes detectable by an x-ray system if it has a high atomic mass; this is a feature generally related to the contaminant's density. Some contaminants, such as mineral stone or glass, may contain trace amounts of elements with very high atomic numbers. These elements have a multiplying effect on the contaminant's x-ray absorption, (see Section 6.1).

Food products generally contain low atomic mass elements and have low density, while contaminants usually contain high atomic mass number elements and have a higher density. For this reason, it's convenient to use density as the benchmark for contaminant detection. In general, contamination detection is only possible where contaminants are denser (i.e. they have higher specific gravity) than the food product in which they're embedded.

Typical Food Contaminant	Typical Density [kg/m³]	Detectability
Gold	19.30	Easily Detectable
Lead	11.30	
Copper	8.92	
Stainless Steel	7.93	
Steel	7.86	
Iron	7.15	
Aluminum	2.71	Detectable
Glass	2.40 – 2.80	
Stone	2.30 – 3.00	
Bone	2.20	
PTFE	2.19	Somewhat Detectable
PVC	1.5	
Acetal	1.31	Not Detectable
Polycarbonate	1.20	
Nylon	1.15	
Water	1.00	Typical Food
Polypropylene	0.90	Typically Not Detectable
Wood	0.65	
Insects	0.59	
Cherry Pit	0.56	
Hair	0.32	

Table 1.1

Many foods are water-based, so they have a relative density similar to water (1000kg/m3). Expressed in specific gravity terms, this is an SG of 1.0, which is usually taken as the datum or reference point (Table 1.1).

A process known as 'relative absorption' is at the heart of x-ray-based inspection technology; referring to the different amounts of x-rays that different materials absorb and allow to pass through them, it's the factor that determines the sensitivity and performance of all x-ray inspection systems.

Some items in Table 1.1 are typically not detectable; their density is less than (or too close to) that of the food product. Moving further up the table, the densities increase. Items higher up the table absorb more x-ray energy and are more easily detected. That also means smaller particles of those items can be detected.

Wood, for example, is very hard, but not very dense, and therefore is usually not detectable. Most plastics are also very hard but show densities similar to water, which makes them hard to detect in products with densities similar to water. For these reasons, it can be seen that x-ray technology is not a 'magic box'; it will not detect everything – but it is very effective at detecting dense contaminants.

Ferrous metals, most non-ferrous metals, and stainless steel all have specific gravities between 7.0 and 8.0; hence these three metals are detectable at the same sensitivities (sizes). Aluminum, which has an SG of 2.71, is a low-density metal, and is x-ray detectable at levels (sizes) similar to glass and stone, which have similar densities.

One of x-ray's great strengths is that it can work extremely effectively at detecting dense contaminants in packaging composed of aluminum foil or metalized film. Since the foil or film is extremely thin, it absorbs very little x-ray energy; in effect, therefore, it becomes invisible to the x-ray. Most x-ray systems sold worldwide to the food industry inspect for metal contaminants in foil or metalized film packages, where stainless steel detection is the most common target.

In summary, x-ray works very well at detecting ferrous metals, non-ferrous metals and stainless steel, as well as glass and mineral stone contaminants. For further discussions on other factors affecting sensitivity of detection, see Chapter 6.

1.7 Image Creation and Contamination Inspection

The x-ray system is essentially a scanning device. It captures an image of an entire pack when the product passes through the x-ray beam at a constant speed. To maintain the correct aspect ratio of the image (i.e. the correct proportions of the image), x-ray systems automatically link the detector scanning speed to the speed of the throughput conveyor. If the product speed is variable, then the x-ray system should provide for an external encoder input to synchronize the detector scanning speed to the belt speed.

With a detector diode size of 0.8mm, for example, a new line of image data will be acquired for every 0.8mm of product movement in the direction of flow (Figure 1.4). Once the data is compressed and corrected, all the pixels will have a value in the range 0 (black) through to 255 (white). Typically, the product will be represented in the gray level range of 50 to 200. (See section 7.2)

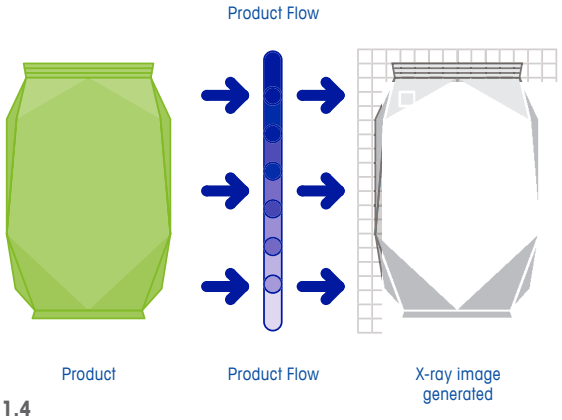

Figure 1.4

These lines build up sequentially to form the overall image of the pack. Once the entire image is acquired for the pack, the software detection tools examine it for anomalies. Typically, a learning process is performed using between 5 and 10 known good products to 'teach' the software what to look out for. Once the good samples have passed through the system, the software sets all the inspection algorithms to these acceptable levels, with a built-in offset to account for the small sample base.

Threshold Image Analysis

Thresholding is the most basic form of contamination detection. This technique records the densest area in the image (the darkest pixel with the lowest pixel value) and primarily inspects for contaminants significantly more dense than the product. Thresholding is adaptive: it changes with the product signal and is ideal for homogeneous packs (e.g. a retail block of cheese whose contents are the same throughout). It doesn't matter where a contaminant is in the homogeneous pack, as it will always have the same combined absorption signal within the product.

Radial Image Analysis

This is now the most common and most flexible contamination detection method used. It works by comparing the value of each pixel to those of its neighboring pixels. Each pixel value is analyzed and a truth-table calculation is performed (a 'truth table' lists all possible combinations of truth values). Superior x-ray systems will have multiple inspection routines or 'tools' running simultaneously. Each will be looking for different sizes or profiles of contaminant. Multiple tools provide improved levels of detection and security.

How these tools handle changes in product profiles, and how the achievable level of sensitivity is affected, is discussed in more detail in Chapter 6.

Specialist Tools

For complex packaging types such as cans and glass jars, special contamination tools are available to detect contaminants on the edges of the packaging. Complex software algorithms are used to inspect the packs and can be instructed to inspect only detailed areas of the packs.

1.8 References

Links to various sources of information are included below for reference:

SI metric – A comprehensive list of SG values for all common metals and materials

http://www.simetric.co.uk/si_metals.htm
http://www.simetric.co.uk/si_materials.htm

Safety of Food X-ray Inspection

The very word 'radiation' can awaken all sorts of reactions in people – and given its role in science, medicine and world history, radiation is (quite rightly) an emotive subject. Unfortunately, radiation is often misunderstood. While people are right to be wary of radiation, the fact is that a factory containing correctly maintained and well-managed x-ray equipment is as safe as any other properly controlled and monitored working environment.

Some food manufacturers have reservations about the adoption of x-ray inspection as a method of product inspection. They are concerned that their staff will object to bringing x-rays into the workplace and that consumers could switch to another brand that hasn't been subjected to x-ray inspection. People are cautious about radiation, but that doesn't mean they should be worried about the use of x-rays in food inspection.

The levels of radiation used for x-ray inspection in the food industry are extremely low, and the use of x-ray inspection equipment is both highly regulated and increasingly common. Food manufacturers use x-ray inspection technology to ensure product safety and quality, and x-ray inspection gives them exceptional levels of metal detection for ferrous metal, non-ferrous metal, and stainless-steel. The technology is also extremely good at detecting other foreign bodies such as glass, mineral stone, calcified bone, and high-density plastics and rubber compounds.

In addition, x-ray systems can simultaneously perform a wide range of in-line quality checks such as measuring mass, counting components, identifying missing or broken products, monitoring fill levels, measuring head space, inspecting seal integrity, and checking for damaged product and packaging.

This chapter covers the health and safety aspects of radiation, and puts permitted radiation limits in the context of everyday exposure to different radiation sources, both natural and man-made.

2.1 Radiation Basics

Energy from a given source is generally referred to as 'radiation' – and different forms of radiation have been harnessed by science for use in many different types of equipment that we now take for granted in everyday life.

There are two main sources of radiation: natural and man-made. Examples of both types of radiation include natural heat or light from the sun (and beyond), radiation from the ground, and gamma rays from radioactive elements. Man-made radiation includes microwaves from an oven and x-rays from an x-ray tube.

Most parts of the electromagnetic spectrum (Figure 2.1) are used in science for spectroscopic and other probing procedures, in which matter can be studied and characterized through the use of radiation. X-rays are used for many purposes, from medical examinations to the identification of contaminants in foodstuffs and other materials.

The wavelength of x-rays enables them to pass through materials that block out visible light to a greater or lesser degree. The transparency of a material to x-rays is broadly related to its density, which is why x-ray inspection is so useful in the food industry: the denser the material, the fewer x-rays can pass through. Hidden contaminants, such as glass and metal, show up under x-ray inspection because they reflect more x-rays than the surrounding food.

X-rays used in food inspection systems should not be associated with radioactive materials such as uranium. Radioactive materials are physical sources of radiation, and they emit radiation in the form of alpha particles, beta particles, and gamma rays. They do so continuously, which is why they cannot be switched off – and the only way to contain radiation from a radioactive material is to encase it in a substance (such as lead) that absorbs radiation.

X-rays used in food inspection are different; like light from a bulb, they can be turned on and off at will. Switch off the electricity supply to the x-ray system, and the flow of x-rays ceases instantaneously.

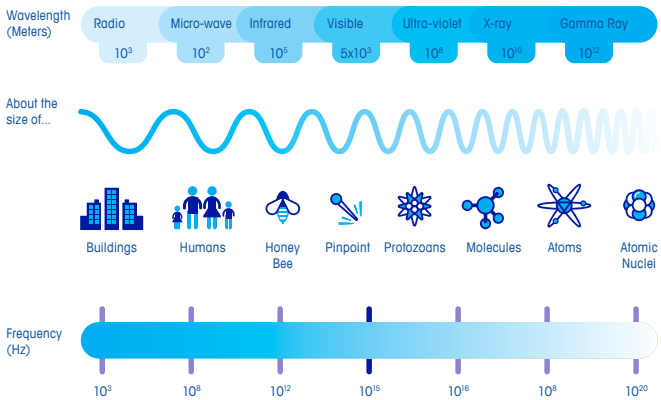

Figure 2.1

2.1.1 Ionizing Radiation

An ion is an atom or molecule in which the total number of electrons is not equal to the total number of protons (i.e. there are more electrons than protons, or more protons than electrons). This gives the atom a net positive electrical charge (when there are more protons), or negative electrical charge, (when there are more electrons).

Ionizing radiation is radiation that has enough energy to force electrons out of atoms to create ions. X-rays are a form of ionizing radiation within the electromagnetic spectrum, and they have the ability to penetrate both synthetic and biological matter.

Other forms of ionizing radiation include alpha particles, beta particles and gamma rays, all of which are emitted by radioactive materials or sources. However, since radioactive materials are not used in x-ray inspection systems, their effects and applications are not covered by this guide.

2.1.2 Background Radiation

Background radiation is all around us, and it includes radiation from both natural and artificial sources. As humans, we've always been exposed to radiation from the environment in which we live; in fact natural sources account for approximately 80% of the total radiation that we receive (Figure 2.2).

Radon Gas

Radium-226 is a chemical element, and all isotopes (variants) of radium are highly radioactive, with the most stable isotope being radium-226, which has a half-life (the amount of time required for it to halve in value) of 1600 years. This decays into radon gas. Many soils and rocks (particularly granite) naturally contain radium, which seeps out of these naturally-occurring materials in a gaseous form. Radon is often the single largest contributor to an individual's background radiation dose, and the proportion is typically around 50%, but it varies widely from location to location throughout the world.

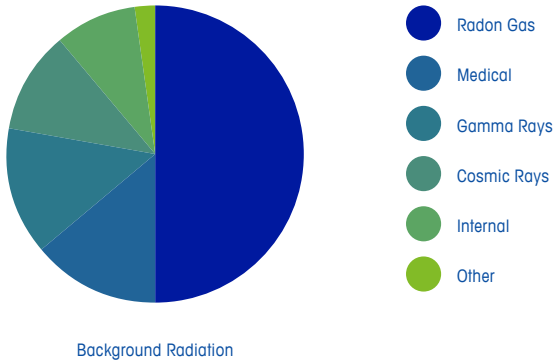

Figure 2.2

Cosmic Radiation

The earth, and all living things on it, is exposed to radiation that originates from outside the solar system. Cosmic rays comprise chiefly protons, alpha particles, and other atomic nuclei, but include some high-energy electrons. When cosmic rays enter the atmosphere, some are filtered out, while others collide with atomic nuclei, and produce secondary radiation such as pions, muons, electrons, and gamma rays.

Internal Radiation

This type of exposure arises when a person inhales or ingests radioactive material, normally in the form of a very fine dust. The various organs of the body then receive a radiation dose emitted by the radioactive material.

Medical Radiation

The main source of artificial radiation (contributing to 15% of all background radiation exposure) is from medical x-rays such as chest and dental x-rays.

2.1.3 Radiation Dose, Quantities and Units

Where people are working in an environment which involves the use of radiation, the accrued radiation dose that individuals receive is the most important measure. These 'occupational exposure' limits are given in terms of the permitted maximum dose of radiation.

The unit of radiation dose is the sievert (Sv), which is named after Professor Rolf Maximilian Sievert, a medical physicist who studied the biological effects of radiation. As occupational exposure levels are normally low, smaller units – millisievert (mSv: a thousandth of a sievert) or microsievert (µSv: a millionth of a sievert) – are more commonly used.

The radiation dose rate measures the rate at which radiation is absorbed over time. This is expressed in µSv/h. Dose Rate = Dose (µSv) ÷ Time (hours).

2.2 Putting Radiation Quantities into Context

To understand radiation levels, it is important to compare dose rates from some natural and artificial sources of radiation that we are exposed to in day-to-day life (Figures 2.3 to 2.5).

Figure 2.3

Eat one average 150-gram banana each day for a year = 36.5 µSv/year.

Figure 2.4

Frequent fliers = 200 µSv/year. Airline pilots and air crew = 2000 µSv/year.

Figure 2.5

Maximum permitted leakage levels from an x-ray system = 1 µSv/hour (ROW regulations), 5 µSv/hour (US regulations).

Each member of the world population is exposed, on average, to 2400 µSv a year of ionizing radiation from natural sources. Typically, this far exceeds the radiation exposure received from a properly installed and maintained x-ray inspection system.

2.3 Food Irradiation

The irradiation of food doesn't cause it to become radioactive, just as a person doesn't become radioactive after having a chest x-ray.

Food irradiation, which is regulated by the FDA (the USA's Food & Drug Administration) and WHO (the World Health Organization), involves exposing food to a radiant source, such as x-rays. The benefits include extended shelf-life, improved product quality (because ripening is delayed) and reduction in the number of micro-organisms present. A WHO study in 1997 confirmed that food radiation levels up to 10 kGy (10,000 gray) did not affect its safety or nutritional value.

The 'gray' (Gy) is a measure of the absorbed dose of radiation, and is defined as the absorption of one joule of radiation energy by one kilogram of matter. One gray is equivalent to one sievert.

The FDA doesn't regard a dose below 1 kGy as an irradiation process. For example, to kill salmonella in fresh chicken requires a dose of up to 4.5 kGy, which is about 7 million times more radiation than a single chest x-ray. The radiation dose received by objects scanned by an x-ray system is typically 200 µGRAY (i.e. 200 micro-grays, each micro-gray measuring a millionth of a gray) or less – a level that is too low to affect the safety or nutritional value of food. Organic food producers, and others who may be concerned about the implications of irradiation, will be reassured to know that this low-level dose is less than background radiation, and has absolutely no effect on the food product.

In the UK, the Food Standards Agency (FSA) conducts independent nationwide reports on radioactivity in food. The survey measured radioactivity from different parts of the food chain, including radioactivity levels applicable to people who live close to nuclear sites and eat local food.

The FSA combined this data with radiation levels from possible exposure to other authorized radioactive discharges. The report found that the total UK dose is under the EU annual dose limit for members of the public. That annual dose limit is 1 millisievert (a thousandth of a sievert) for all exposures to radiation.

2.4 Working with X-ray Inspection Systems

X-ray radiation has practical uses in medicine, research, and product inspection applications, where it can be used safely for many valuable purposes. However, if utilized improperly, it can present a health hazard to humans.

It's sometimes assumed that any dose of radiation, no matter how small, is a health risk. However, there's no scientific evidence of any health risk at doses below 20,000 µSv a year, which is the adult limit for occupational radiation exposure when working with radioactive material.

Modern x-ray systems for food and pharmaceutical applications don't contain sources of live radiation, such as uranium; in fact they are designed to provide a perfectly safe working environment for operators. Provided safety guidelines are followed, there are no restrictions for anyone, including pregnant women and young adults, operating this type of equipment.

The x-rays within an x-ray inspection system are electrically generated, which means they can be turned on and off. This differs from radiation sources (such as uranium), which naturally emit radiation in the form of alpha, beta or gamma rays. These sources can only be made safe by proper containment.

2.4.1 Protection Principles

To protect the user from the effects of radiation, x-ray inspection systems are safe because they have been specifically designed with safety in mind. That's why they are designed with the x-ray generator installed in an enclosure; this is known as a 'cabinet system'.

It's still worth bearing in mind that the risk of being exposed to radiation can be controlled through a series of protection principles: time, distance and shielding, as follows:

1. Time

For people who are exposed to radiation over and above natural background radiation, limiting or minimizing exposure time will reduce the dose. The dose rate is directly proportional to the amount of time spent in a given location.

Dose rate (µSv/Hour) = Dose ÷ Time
(The relevance is discussed further in Section 4.3.1)

2. Distance

The intensity of radiation from an x-ray source decreases in proportion to the inverse of the square of the distance from it. This principle is commonly known as the Inverse Square Law. Dose Rate is proportional to 1 ÷ (Distance)2.

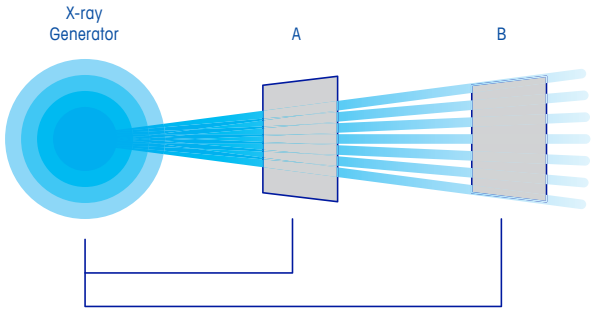

Figure 2.6

For example (Figure 2.6), if the radiation dose rate measured at A (a meter from the x-ray source) is assigned a value of 1 (1 ÷ 12); at B (two meters from the source) it will be 0.25 (1 ÷ 22), i.e. a quarter of the dose rate at A (the relevance is discussed further in Section 4.3.1).

3. Shielding

As already discussed in Chapter 1, x-rays are absorbed when they pass through a material. The most efficient absorbers of x-rays are highly dense materials (Figure 2.7) – which is why x-ray machines are often made from stainless steel, while the design of some x-ray generators incorporate copper for additional containment of the x-rays (the relevance is discussed further in Section 4.3.1).

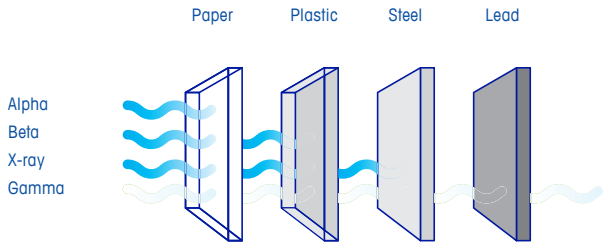

Figure 2.7

2.4.2 X-ray Inspection System Safety

When using x-rays for product inspection, the x-ray system must be built to comply with safety standards such as the Ionizing Radiation Regulations 1999 and the American Standard 1020.40 CFR. Meeting safety standards ensures that all personnel and production staff are safe when operating the machine, providing everyone follows the safety procedures. For this reason, x-ray inspection systems should be built utilizing the following safety requirements:

- All systems should be fully CE certified.
- All systems must adhere to local rules and regulations – for example, in the UK, all systems should comply with the Ionizing Radiation Regulations 1999.
- Maximum allowable radiation leakage levels should not exceed 1 µSv/hour (ROW regulations), 5 µSv/hour (US regulations).
- Once installed and a certificate is issued, all x-ray systems are subject to a final critical radiation survey, to prevent accidental exposure.

2.5 References

The Health Protection Agency – Radiation Safety in the UK
http://www.hpa.org.uk/radiation

Food Standards Agency
http://www.food.gov.uk

US Food and Drug Administration (FDA) – main regulatory body for the United States
http://www.fda.gov

World Health Organization (WHO)
http://www.who.int/

FAO/WHO Food Standards
http://www.codexalimentarius.org/

Health & Safety Executive UK – Safety advice on working with ionizing radiation
http://www.hse.gov.uk/radiation/ionising/

Soil Association
http://www.soilassociation.org

Notes

Metal Detection, X-ray Inspection or Both Technologies?

The quality and safety of food and pharmaceutical products depends on the due diligence exercised during the production process, in order to exclude contaminants from finished products.

Food manufacturers must comply with regulations to prevent contamination, such as the Global Food Safety Initiative (GFSI), the British Retail Consortium (BRC), Food Safety System Certification 22000 (FSSC22000) and International Feature Standard for Food (IFS). Pharmaceutical manufacturers have their own compliance requirements. The choice of protection and inspection equipment hugely affects product quality, product safety and consumer confidence. Manufacturers must decide whether to install an x-ray inspection system, a metal detection system, or both – and this chapter compares the two.

3.1 The Capabilities of X-ray Inspection and Metal Detection Systems

Metal detection and x-ray inspection systems can be installed at Critical Control Points (CCP) to inspect in-coming raw materials prior to processing – or at numerous other points in the manufacturing process. Inspection systems can also be installed at the end of the production or packing line. Modern metal detectors can identify all metals, including ferrous (chrome, steel, etc.), non-ferrous (brass, aluminum, etc.), as well as both magnetic and non-magnetic stainless steels in food and pharmaceutical products.

As discussed in Chapter 1, x-ray systems are capable of detecting metal, as well as non-metallic contaminants such as glass, mineral stone, calcified bone, high-density plastics and rubber compounds. They can also simultaneously perform a wide range of in-line quality checks such as:

- Measuring mass
- Counting components
- Identifying missing or broken products
- Monitoring fill levels
- Measuring head space
- Inspecting seal integrity
- Checking for damaged product and packaging

Metal detection and x-ray inspection systems can also be used to inspect unpackaged or packaged products. X-ray technology is commonly used to inspect metal cans and products packed in foil or metalized film. However, the latest metal detection technology now makes it possible to inspect products packaged in metalized film with improved results approaching that of an x-ray system in certain applications for the detection of metal contaminants.

Furthermore, both technologies can be used to inspect liquids, pastes and slurries in pipeline applications.

3.2 Product Effects

The effect of the products being tested will depend upon the chosen inspection technology; both metal detectors and x-ray systems have differing inspection capabilities which directly impact sensitivity.

Historically, detecting small contaminants in products with high moisture content have been challenging for metal detectors as the signal given off from the product, known as the product effect, has masked the signal given off by the metal contaminant. However, with the development of Multi Simultaneous Frequency (MSF) technology this effect is considerably reduced and previously challenging products are now easily inspected, with the result being a vastly improved level of sensitivity.

The ease with which contaminants can be identified by x-ray inspection depends on various factors such as product density, product depth and product homogeneity. A detailed explanation is available in Chapter 6 of this guide.

In general, as the product size increases both metal detection and x-ray inspection technologies will experience a reduction in sensitivity levels. It is therefore recommended that a product test is performed in all cases to determine the most suitable technology.

3.3 Packaging Effects

The packaging material of a product can impact detection levels to a differing degree, depending upon the inspection technology used.

Both metal detection and x-ray inspection technologies are commonly used to inspect a vast array of packaging types/ materials that are frequently used in the food and pharmaceutical industries, these include:

- Plastic trays or overwrap
- Paper
- Metalized film
- Aluminum foil
- Glass
- Metal cans
- Ceramic pots
- Doypacks
- Composite cartons/ tubes

3.3.1 Metalized Film Packaging

Products packaged in metalized film can usually be effectively inspected by metal detectors using low-frequency operation (depending on the film thickness). However, as mentioned in section 3.2 MSF technology is now available from some metal detection companies, offering improved sensitivity.

In some cases however, if the metalized film is particularly thick, it is preferable to inspect these products prior to packing by using a "Throat" type metal detector. Alternatively, an end of line x-ray inspection system can be utilized on the final packaged product.

There is no measurable impact on detection levels using x-ray inspection systems when inspecting products packaged in metalized film.

3.3.2 Aluminum Foil Packaging

Aluminum packaging, such as foil wraps and product trays, are a bigger challenge for metal detectors. Detectors using balanced coil technology are unable to inspect products in aluminum packaging – so a different technology, known as 'ferrous-in-foil' detection, must be used. The drawback here is that this technology can only detect magnetic metals and may not be an acceptable solution.

A major application area in which x-ray inspection ex, over traditional metal detection technologies, is when inspecting products packed in aluminum foil. Due to the way in which the x-ray system works this packaging material has a negligible impact on detection levels.

3.3.3 Aluminum Contaminants in Non-Metal Packaging

Aluminum is a lightweight metal and a good electrical conductor. Since its density is lower compared to other metals such as ferrous and stainless steel, this does cause a reduction in the sensitivity on an x-ray inspection system (see Chapter 1 for further information), meaning aluminum is detected at approximately twice the size of ferrous or stainless steel. Due to its excellent conduction properties aluminum can often be detected at smaller sizes using metal detection technology in non-metal packaging.

3.3.4 Metal Contaminants in Non-Metal Packaging

When looking only for metal contaminants and cost is a major factor when making a purchasing decision, then metal detectors can provide the most appropriate solution. However, if the requirement is to detect metal contaminants while simultaneously conducting in-line product integrity checks, x-ray systems are the appropriate solution. If there are any doubts a product test would always be advisable.

3.3.5 Metal Contaminants in Gravity-Fed Products

Gravity-fed, powdered or granular products don't travel at the same speed; they accelerate as they fall, plus the direction of travel is not uniform, since they bounce off each other. X-ray inspection systems can't yet offer a satisfactory solution when handling this type of product, so metal detection is currently the preferred solution and as the product tends to be dry and non-conductive the sensitivity levels achieved are good.

3.3.6 Non-Metal Contaminants in Any Packaging

X-ray inspection is the only solution, and has the ability to detect non-metallic contaminants such as glass, mineral stone, calcified bone, and high-density rubber and plastic.

3.3.7 Product Size Limitations

Both x-ray and metal detectors can be designed to accommodate any product size. For larger packs and products, the aperture height must be increased and, as a general rule, the larger the aperture height and product, the lower the sensitivity.

3.4 Which Technology – Metal Detection and / or X-ray Inspection or Both?

Metal detection and x-ray inspection offer different capabilities – and in order to assess those capabilities fully, the first step is to carry out a Hazard Analysis and Critical Control Points (HACCP) audit. This will help to understand the requirements of any customer or compliance-related issues driven by the GFSI and/or major retail groups.

A HACCP audit will identify the risks of contamination being introduced into the manufacturing process, and the types of contaminants likely to be encountered. Critical Control Points (CCPs) should be established to mitigate the risks, and product inspection equipment needs to be installed at these points to reduce the risk of contamination to acceptable levels.

If the HACCP audit determines that metal is likely to be the only contaminant found, then a metal detector is likely to provide the most cost effective solution, however, as previously mentioned due to factors such as packaging and product effect it is recommended to perform a product test to establish the most suitable technology. If, however, other contaminants like glass, mineral stone, calcified bone or high-density plastics and rubber are identified as likely to be encountered, then x-ray is the only suitable solution.

In many cases, there's only one suitable solution – either metal detection or x-ray inspection. However, there are also occasions when it could be necessary to install both metal detection and x-ray inspection at different CCPs on the same production line.

HACCP and the 'Seven Principles' are explained in the Introduction Chapter and CCPs are discussed in more detail in Chapter 13 of this guide.

3.4.1 Installation and Monitoring Requirements

Metal detection and x-ray inspection systems can be supplied with a variety of product-handling devices, including an array of fully-automatic reject devices. Both metal detection and x-ray inspection systems also require regular performance monitoring checks to be carried out at prescribed intervals. Installation, commissioning and training is explained in more detail in Chapter 15. Recent advances in Metal Detection Technology with the development of Predictive Analytics make it possible to extend the interval between scheduled tests of the metal detector. This in turn can make it very attractive to the user as it gives potential for an increase in the user's OEE percentage.

3.4.2 Quality Control Issues

X-ray inspection systems can perform a wide range of other quality control checks at the same time as contamination detection, including measuring mass, checking fill levels, cap detection, inspecting seal integrity (products or contaminants trapped in the seal) and checking for damaged product or packaging.

Additional features such as these can help food and pharmaceutical manufacturers justify the additional cost of x-ray inspection technology. Chapter 8 includes further information regarding the product integrity check capabilities of x-ray inspection systems in addition to contamination checks.

3.4.3 Fast / Variable Line Speeds

Metal-detection and x-ray inspection systems are both suitable for variable and fast production lines. Metal detectors will detect contaminants in products moving at low and high speeds, including conveyors running at speeds above 400m/min (although very few conveyorized processes run at such high speeds).

X-ray inspection systems can monitor conveyor lines running at up to 120m/min. Even higher inspection volumes/ speeds can be achieved in pumped and bulk applications for both metal detection and x-ray technology. The choice of technology is dependent on multiple factors such as types of contaminant, product type and packaging material; speed generally isn't a deciding factor.

3.4.4 Limited Space

A metal detection search head takes up less space than an x-ray inspection unit, so in situations where installation space is limited and metal is the likely contaminant, a metal detector may be the best solution. If packaged products are being inspected, both systems will normally need a conveyor system and an automated reject system. In some situations, the differences in overall system length can be very small. Some metal detector companies offer what is referred to as Zero Metal Free Zone (ZMFZ) technology. This allows the overall size of the metal detection system to be drastically reduced and it is common place to find metal detection systems that take up less than 1000mm of line space.

In cases where an integrated reject system is not required it is possible to install an x-ray inspection system into a space of less than 1000mm, providing there is adequate local guarding in place.

3.4.5 Industry Standards and Codes of Practice

Recent changes in food and pharmaceutical industry safety standards are resulting in the increased adoption of metal detection and x-ray inspection systems by manufacturers. A growing number of major retailers are setting their own codes of practice, which contain specific advice regarding product inspection equipment; these include the Global Food Safety Initiative (GFSI), the British Retail Consortium (BRC), Food Safety System Certification 22000 (FSSC22000) and International Featured Standard for Food (IFS). In addition, pharmaceutical manufacturers have their own compliance requirements.

3.4.6 Simplifying the Choice

Following the development of both metal detection and x-ray inspection technologies the choices are no longer made by simply choosing one or the other. This chapter is a good starting point for choosing an appropriate technology, but it can't provide all the answers. There's often an area of indecision that requires further levels of discussion with product inspection experts.

If cost is the sole criterion for deciding, metal detection may seem a more suitable solution. However, product safety decisions are rarely that simple. The performance of each solution is affected by the size of the product to be inspected, plus it's important to compare lifetime costs, not just the upfront capital costs.

The type of product and the likely contaminants will also affect the choice; consideration must be given to the HACCP audit and CCPs on the production line. Sometimes, the answer is to install more than one detection system at different CCPs on the same production line.

For example, a metal detector or a bulk flow x-ray inspection system placed early in the processing line can remove large metal or non-metallic contaminants before they reach delicate machinery downstream, where they could damage the machine or become fragmented into multiple, smaller, more difficult to detect contaminants.

As well as protecting the machinery, the inspection equipment will remove contaminants before further processing increases the cost of product waste.

4 Summary Table

The following table summarizes the key differences between the two technologies:

	Metal Detection	X-ray Inspection
Product formats	Packaged, conveyorized products, loose, bulk products, free-falling and vertically-packed products (including powders and granular products), pumped liquids, pastes and slurries, continuous web products	Packaged, conveyorized products, loose, bulk products, pumped liquids, pastes and slurries, continuous web products
Contamination detection	Detection of all metal contaminants, including ferrous, non-ferrous (including aluminum) and magnetic and non-magnetic stainless steels	Detection of dense contaminants like ferrous, non ferrous and stainless-steel, as well as other contaminants like glass, stone, bone, high-density plastics and rubber compounds
Detectable contaminants	Contaminants must be austenitic (magnetizable) or electrically conductive	Contaminants must be high-density or have a high atomic mass number
Aluminum contaminants	Easily detected	Detectable, but not as easily detected as other metals
Quality checks	Detection of metal contaminants	Detection of dense contaminants and simultaneous quality checks for mass measurement, seal inspection, fill-level control, component count,detection of missing and broken products, as well as packaging
Product texture	No effects	May limit performance
Conductive product	Can be inspected	Can be inspected
Metalized film-packed products	Can be inspected	Can be inspected
Aluminum foil-packed products	Cannot be inspected	Can be inspected
Pack size effects	The larger the pack, the less sensitive	The larger the pack, the less sensitive
Increased aperture size	Sensitivity can decline, and costs increase moderately	Sensitivity can decline, and costs increase significantly
Short Conveyor length	Short conveyor lengths or space required for insertion	Short conveyor length may need special guarding for radiation safety
High line speeds	Operates at high line speeds	Operates at high line speeds
Variable line speeds	Operates at variable line speeds	Operates at variable line speeds

Table 3.1

Notes

Choosing the Right X-ray System for Your Application

Choosing the right kind of x-ray inspection system is fundamental to the success of a rigorous and in-depth inspection program. X-ray inspection equipment can't address contamination or production problems unless each element of the system has been carefully chosen to fit the specific line and the particular product.

An understanding of the various formats of x-ray inspection system (and their suitability for different types of detection challenges) underpins system specification and choice.

Factors that should be considered when specifying an x-ray inspection machine include:

- Application (product and packaging type)
- Installation environment
- Desired sensitivity
- Best practice
- Accepted codes of practice

It's important to take the time to make a careful selection and a balanced choice, since the effort involved will be rewarded by:

- Easy installation
- Avoidance of major modifications after integration
- Maximum operational efficiency
- Ease of verification testing

X-ray systems fall into three categories (or three types of cabinet systems): vertical beam systems, horizontal beam systems, and systems that are a combination of the two. This chapter discusses:

- The differences between these three systems.
- How to choose the correct x-ray machine and reject system.
- Production-line integration (especially where product-handling may be difficult).
- The incorporation of failsafe features.

4.1 Vertical Beam Systems

X-ray inspection systems using vertical beams are most commonly used on production lines. This is because most fast-moving consumer goods are usually smaller in depth (i.e. height) than they are in width and length, so inspecting them through the vertical cross-section (which has the least product depth) provides the best sensitivity.

4.1.1 Machines for Sealed Packs

The x-ray machine includes its own conveyor, and it transports packs from the manufacturer's line, through the x-ray beam, and then back onto the line (Figure 4.1). As with all x-ray systems, an automatic reject system can be fitted so that faulty packs can be removed efficiently from the line.

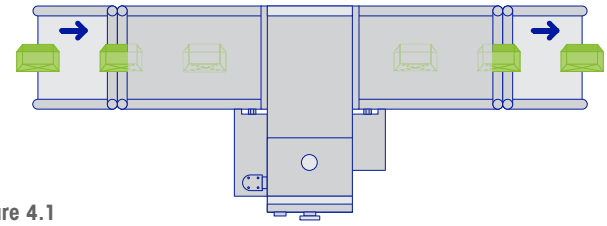

Figure 4.1

Since the x-ray generator is typically mounted in the top of the cabinet, the beam shoots downwards through both the product and the belt, before striking the detector. The beam is up to 8mm wide, across the conveyor – and is triangular in its vertical cross-section. It diverges from a small point within the x-ray source before passing through the collimator, to its widest point across the width of the conveyor on the belt surface (Figure 4.2).

The image created from a vertical beam is a plan view of the pack, which makes it easy to see the internal components. This view allows for detailed analysis of the pack (this is discussed further in Chapter 8).

To ensure inspection of the entire product, each pack should fit within the triangular-shaped vertical beam. Packs should be guided to the center line of the belt, and should be positioned on the center line of the belt. The largest width and depth of pack to be inspected determines the size of the x-ray beam; this, in turn, dictates the aperture size and scan width of the machine.

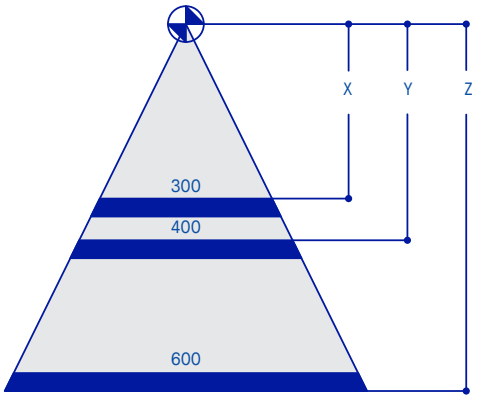

Figure 4.2

To create a wider triangular x-ray beam for wider or deeper packs, the focal distance (i.e. the height from the exit of the x-ray generator to the surface of the imaging detector) needs to be greater. A range of different widths of conveyorized vertical beam systems is available, covering different applications. These can vary from small blister packs and medium-sized ready meals to large transit baking trays.

When products are contained in a tall and wide case, effective inspection may require an arrangement of two vertical beams; together, they provide complete coverage across the entire width and depth of the pack (Figure 4.3).

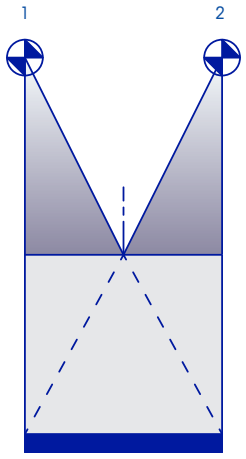

Figure 4.3

For individual detectors, there's a choice of different generator sizes, which create different power levels. Selection of the right power level is made on the basis of achieving the best penetration and gray-scale x-ray image contrast, bearing in mind the density of the packaging and the product.

4.1.2 Bulk-Flow Machines

Bulk-flow x-ray systems can inspect wet, dry, free-flowing loose products before they are packaged or added, as an ingredient, to a finished product. Typical applications include grains, peanuts, extruded snacks, dried fruits, vegetables and pulses. Sensitivity of detection in bulk-flow products is usually better than in final closed packs, because the depth of product is typically much less. Ideally, therefore, a single homogeneous layer of product (around 25mm deep or less) or a constant depth of product flow should be achieved, in order to obtain the best inspection results.

Consideration should be given to the location of inspection machines in the production line. When they are placed towards the beginning of the production-line process, they can inspect incoming goods or raw materials for contaminants. This inspection takes place when those contaminants will be at their largest and most easily detectable. Contaminants can then be removed at source and immediately traced back to the supplier. By contrast, contaminants further downstream along the production line may break into smaller, less detectable fragments as a result of the manufacturing process.

Early removal of contaminants also protects equipment downstream, preventing expensive machine damage, downtime and possible further contamination of the product from damaged machine parts. It also means that contaminants can be removed before further value is added to the product.

Key design features on bulk flow machines include:

- A beryllium-window x-ray tube (see Chapter 5.5).
- A conveyor (of a type which matches the production line).
- An appropriate reject system.

4.1.3 Pipeline Machines

Pipeline machines are designed for inspection of pumped products (such as liquids, slurries and pastes) before final packaging and further value is added to the product. Applications typically include sauces, jams, whole muscle or ground meat, chocolate, and dairy spreads, but also include products that can't be sieved such as textured fruit purees, dairy spreads, and yogurts containing fruit chunks.

Product is fed through the manufacturer's pipe, which is attached (using standard fittings) to the manifold section of the x-ray machine. Typically, the manifold tapers the round pipe to a smaller rectangular inspection window. This is where the beam scans the product as it passes through. If any contaminated product is detected, this is diverted away via a reject diverter valve.

Care should be taken to eliminate air bubbles from the product, which can cause false rejections. A good pump and feed design can overcome this potential problem, and the use of a positive-pressure vacuum pump is recommended, because it produces a constant flow rate with minimal air bubbles. A well-designed system will allow for variation of the scan speed (and associated automatic reject timing) by simply taking an encoder signal from the manufacturer's pump.

Like bulk machines, the x-ray pipeline system is usually located upstream on the production line, so that it can inspect product at an early stage and detect contaminants before they break down and/or damage machinery further along the production process.

The x-ray pipeline system offers excellent detection levels because the product is homogeneous and is usually pumped through a 50mm-deep (or less) inspection manifold. It's much easier to find a contaminant in a pipeline system before the product fills glass jars; however, glass packaging carries its own risks, so there may be a need for more than one Critical Control Point on a line (see Chapter 13).

4.2 Horizontal Beam Systems – Packaged Product in Tall, Rigid Containers

Horizontal beam x-ray systems are primarily used for products in packs, where the height of the pack is greater than its width (tall, rigid containers). Since a key factor in detection sensitivity is the depth of product through which the x-rays must pass, a horizontal scan usually results in better detection rates for these kinds of packs – which means that the x-ray generator is mounted in the side of the machine cabinet and scans through the side of the container (Figure 4.4).

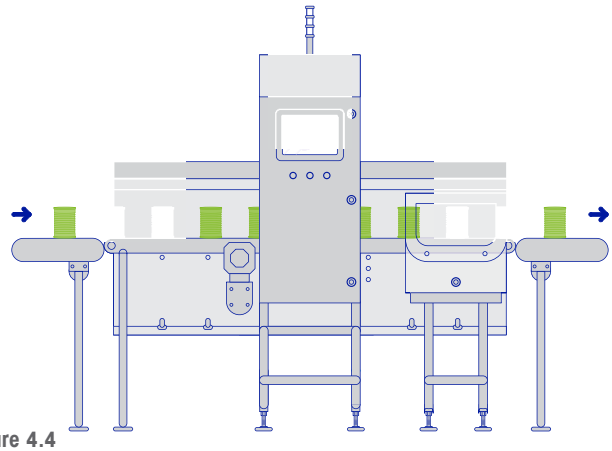

Figure 4.4

A side-shot image allows easy application of dynamic software filters to the densest areas of the image – which is usually the perimeter of the packaging. This optimizes detection levels and ensures minimum false rejection rates. Dynamic software filters are particularly important when inspecting metal cans or glass and ceramic containers.

Different-sized generators and different types of detectors can be used to obtain the optimum detection set-up. Furthermore, multiple x-ray generators and detectors can be used in the horizontal plane; alternatively, they can be combined with an additional generator and detector in the vertical plane.

Within this guide, tall, rigid containers are sub-divided into three categories. These categories are based on the density of the packaging used. The categories illustrate the possible systems available, and how they can be applied to ensure optimum results.

4.2.1 Low Density Packaging

Low-density packaging such as cartons, plastic bottles, composite cans and doypacks presents fewer challenges to the x-ray system, due to the fact that the container material absorbs low amounts of x-ray energy. An x-ray system with a single horizontal beam is best suited to detecting physical contaminants and quality defects in products packaged in low-density packaging.

A single horizontal-beam x-ray system has one x-ray generator; this creates an x-ray beam that skims across the surface of the conveyor belt. The system scans the product packs as they pass through a single detector set (Figure 4.5) – and since the beam must be wide enough to encompass the largest container, a variety of sizes of beam geometry is available.

In this set-up, the conveyor used for product transport doesn't affect the x-ray image because it's not in the path of the x-ray beam. Well-designed horizontal x-ray beam systems don't normally involve any disruption of the customer's line; they simply straddle the existing production conveyor and take up

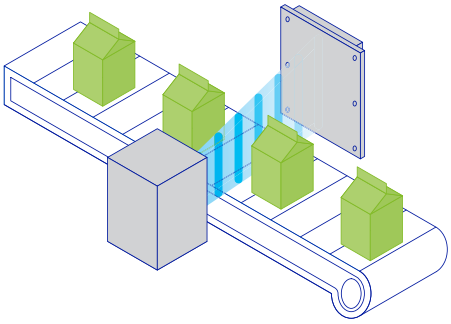

Figure 4.5

minimum line space. This makes for a quick, easy and cost-effective installation without the need to create additional product transfers.

4.2.2 Medium Absorption Packaging

Metal cans are more challenging because the packaging is denser. Metal cans usually contain high-density product and, if the can diameter is large, they put more product in the path of the beam. However, the toughest challenge when inspecting metal cans is to detect small contaminants that are located on the base or side-walls of the can, especially if the can has side-wall ribbing. Ring-pulls can also affect sensitivity, and the best results are achieved when the ring-pull is located on the base of the can.

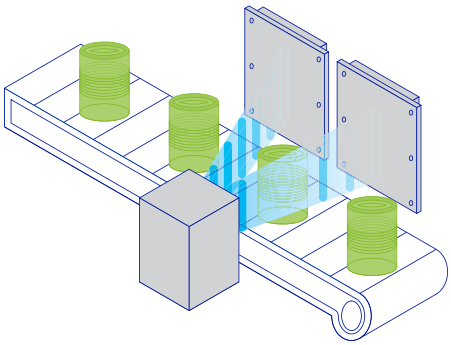

Figure 4.6

A split dual-beam arrangement (Figure 4.6) overcomes this problem. From a single x-ray generator, x-ray radiation is funneled through a dual diverging collimator, creating two beams that are angled away from each other. The beams strike two separate detectors, so that every can is imaged twice. Each image represents a different viewing angle, thus increasing the coverage inside the container and the probability of detection. Contaminants located on the side wall on one image appear nearer the center of the pack on the other image, which makes contaminants easier to detect.

When using multiple beam systems, manufacturers should allow adequate product spacing (known as 'pitching') to ensure that each product can be independently inspected.

Using just one generator maintains a small machine footprint and offers easy installation – without requiring conveyor modifications. Recent advances in imaging software have greatly improved the filtering techniques used in relation to challenging medium-density and high-density containers.

4.2.3 High Absorption Packaging

Glass jars and bottles are perhaps the most difficult type of packaging to inspect. This is mainly because the primary contaminant is glass, which is the same material as the packaging.

However, the type of product being packaged (and its viscosity) has an influence on the possible location of a contaminant – and this needs to be taken into account at an early stage. The filling process of semi-solids or viscous products should be considered first, since a contaminant could be in the container prior to filling. Rapid, high-volume fills of these products can cause a 'wash-out' in the base area, i.e. the flow of the product washes possible contaminants away from the base. In addition, the product flow can lift contaminants higher within the container, where they are then held in suspension. The process actually aids detection via x-ray inspection, but highlights the fact that other areas, as well as the base area, should be inspected (Figure 4.7).

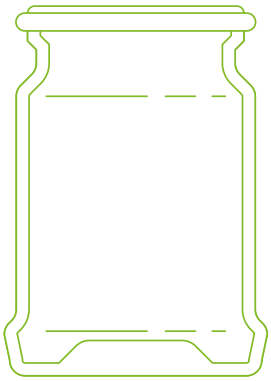

Figure 4.7

Factors influencing the location of contaminants:

- After containers have been filled, glass contaminants are often generated by the capping process.
- A cold fill of a semi-solid or thick particulate product can hold contaminants in suspension; for this reason, the whole container should be inspected.
- A hot fill of a semi-solid or thick particulate produces a less viscous product, so a dense contaminant will move closer to the base.
- In fluids, a contaminant is most likely to be in the container base (also known as the 'crown'), so inspection should be concentrated in that area.
- The lid area of a jar or bottle can be very complex. This part contains elements such as the metal closure, glass screw threads, and variations in glass thickness in the jar shoulder. These features, combined with natural variations in the physical profile of the rest of a glass container (which can be as much as 20%), make glass container inspection extremely challenging.

Single Beam for Glass Jars / Bottles

A single-beam system provides an acceptable level of detection in the body of the jar, but not in the base or top of the container. The base ('crown') is perhaps the biggest challenge, since this can vary greatly – plus it's the densest part of the jar. Contaminants lying in the base channel around the crown can go undetected if they are in front of (or behind) the crown (Figure 4.8).

These contaminants will be hidden in the dark shadow of the crown, which will probably have been filtered out already. It's clear that a single perpendicular horizontal beam offers good detection in the body of the jar, but poor detection in the base and shoulder/cap area.

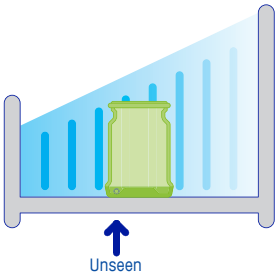

Figure 4.8

Dual Beam for Glass Jars / Bottles

The probability of detection can be improved by using two beams (Figure 4.9). Two separate generators create two separate angled x-ray beams directed towards two detectors. They create images which display the view through the jar from two different angles.

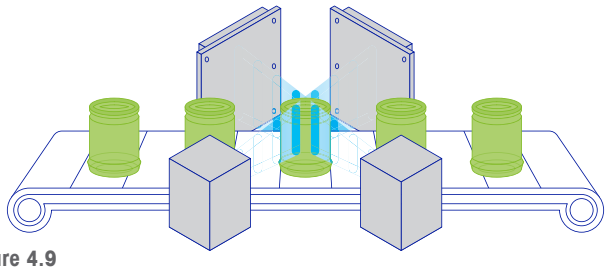

Figure 4.9

A fragment of glass is never a perfect cube or sphere; it's a shard – an irregular shape. The more contaminant that lies in the path of the x-ray beam, the more product is displaced by denser material – which makes it easier to detect. So inspecting the same jar simultaneously from two different angles increases the chance of shard detection.

This double inspection process means that a larger area of the base/crown is inspected. It's also easier to spot contaminants located on the side wall because they appear to be nearer the center of one of the images (Figure 4.10 and 4.11).

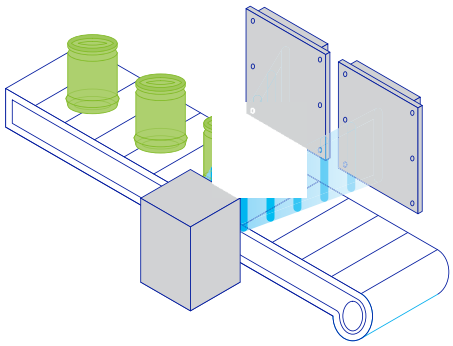

Figure 4.10

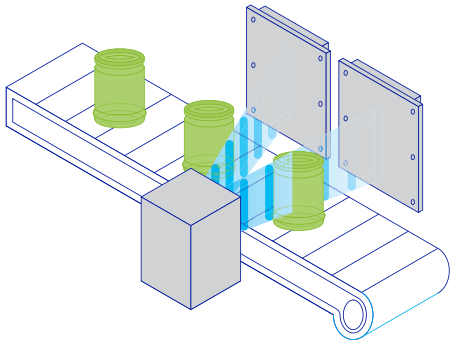

Figure 4.11

Combination Beam Systems for Glass Jars / Bottles

A combination of vertical and horizontal beams is the next step for increasing coverage and optimizing detection in more difficult areas. These are available to the food and pharmaceutical industries, with an optimum x-ray system using a vertical beam and three horizontal beams simultaneously.

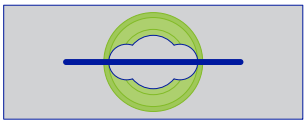

Figure 4.12

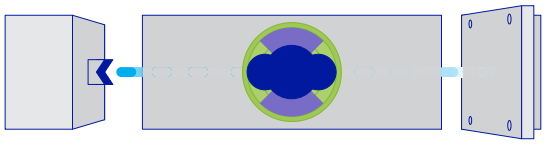

Figure 4.13

Figure 4.12 shows the coverage from a single vertical beam while Figure 4.13 shows the coverage offered if a central perpendicular horizontal beam is added.

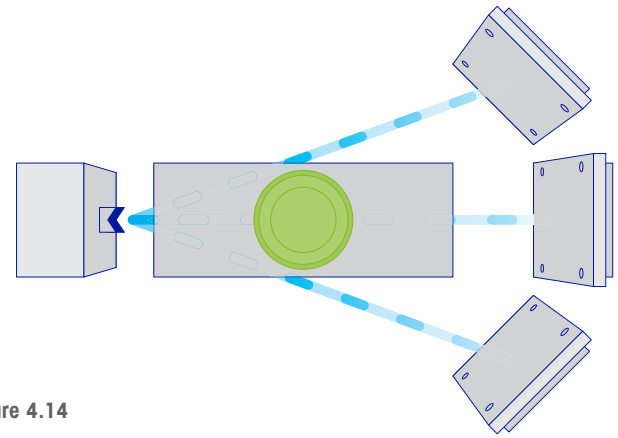

Figure 4.14

Two angled horizontal beams are then added to raise to an absolute optimum the coverage in the base/crown area of the jar – see Figure 4.14.

Single, Perpendicular Angled Beam

Current inspection technology incorporates a single, perpendicular beam that shoots down through the base area while simultaneously inspecting through the side of containers, providing all-round glass-in-glass inspection.

By opening up the base and lower body of glass jars, the crown now appears flat, and traditional blind spots are removed, greatly increasing base detection sensitivity. The beam passes level with the shoulder and top area of the container, below the complex threads and cap. This creates a far less complex image to enhance detection capability.

Systems also provide exceptional full-height fill-level checking, with high accuracy at high speeds, and the position of the generator is vertically-adjustable to suit a wide range of different container sizes. X-ray systems with this technology offer unprecedented opportunities for inspection of a wide-range of food, beverage and pharmaceutical products in containers, as well as a full spectrum of viscosities.

The latest technology removes traditional blind spots, to provide all-round glass-in-glass inspection.

4.3 Transport Systems Designs

A number of designs for transporting the product through the x-ray system are available. These are discussed in more detail below.

4.3.1 Curtain Types

Most x-ray systems make use of tunnel curtains for shielding personnel from x-rays. The curtains hang in the entry and exit apertures of the machine, and comprise strips of a highly x-ray-absorbent material, which are usually laminated in a plastic material. The curtains ensure that the x-ray emissions are restricted to below the acceptable dose-rate level for the country in which the machine is being used, and are suitable for the vast majority of applications. However, they provide a level of resistance to packs passing through them, creating a number of factors that affect the success of product movement.

Packs rely on their momentum to move along the production line successfully, and momentum is generated by a combination of speed of travel, product mass, and the co-efficient of friction between product bases and the belt. When lightweight packs or medium-weight packs with a large surface area (e.g. cereal boxes or tall rigid containers) come into contact with curtains, problems can arise. Another potential difficulty is where packages travel on dirty or wet belts with less grip; these are also less likely to pass through the curtains.

The distance between the top surface of the packs and the point where the curtains hinge is also important; if that distance is too small, the curtains cannot bend and spread out, so the packs will simply become stuck between the conveyor belt and the curtains.

Curtains are not always suitable; in some cases they have to be removed, so emissions must be controlled in another manner:

Option 1 – Generator Activity

Reduce the x-ray activity, i.e. lower the generator power level so that the dose rate at the entry/exit to the machine is reduced to a safe level. However, this leads to low-contrast x-ray images, and so is not a feasible solution.

Option 2 – Exposure Time

Reduce the exposure time of personnel to x-rays, since the less time spent near the source, the smaller dose is received. Although this may sound like a good solution, it's not used in practice because exposure time is difficult to monitor, and regulations restrict usage to 1µSv/Hour in most countries.

Option 3 – Distance

Maintain a straight in-line machine design, and physically extend the x-ray machine tunnel guards (or guard the customer's in-feed and out-feed conveyors) to an equal distance on either side of the primary x-ray beam. Since the x-ray dose rate over distance observes an inverse square law (see Chapter 2.4.1).

Figure 4.15 shows how the dose rate y at a guarded distance x, is reduced by a factor of four, by simply doubling the guarded distance to 2x.

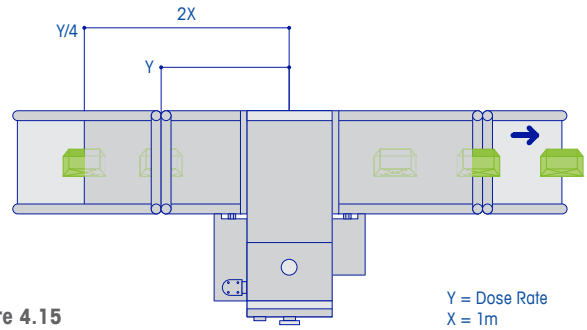

Figure 4.15

It's not always practical to fit guards over a customer's conveyor, because ancillary equipment may be in the way – and since line space is at a premium in most modern factories, a large physical length x-ray system isn't always a possible solution.

Option 4 – Removing the Line of Sight

Since x-rays travel in a straight line, the dose rate can be reduced (or completely removed) by placing a dense material in their path. If curtains can't be used on a vertical beam system, inclining the in-feed and out-feed conveyor section of the machine results in no direct line of sight to the primary x-ray beam. This design contains x-ray emissions because the direct x-ray scatter is shielded by the x-ray guards.

On horizontal x-ray beam systems (where removal of curtains is more prevalent), a simple solution involves side-transferring product by offsetting the x-ray machine from the main production line so that, once again, the direct line of sight to the primary x-ray beam is removed (Figure 4.16).

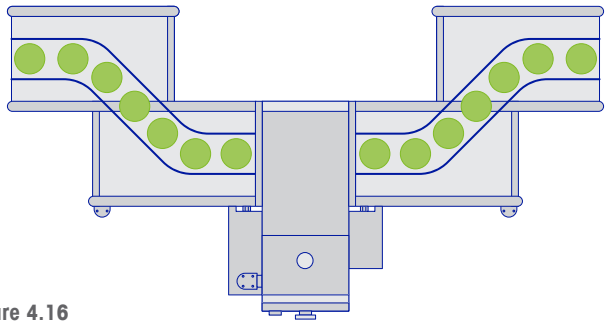

Figure 4.16

4.3.2 Belt Characteristics

A number of factors must be considered when choosing a suitable belt material. On vertical or combination-beam systems, the x-ray beam passes through the product and the belt. The belt absorbs a small amount of the x-ray and is part of the final captured image, so the belt material needs to be low in density. The denser the belt, the less sensitive the detection.

The thickness of the belt also affects the rate of absorption, so the belt must be as thin as possible, yet still strong and durable. The same belt may need to transfer heavy packs at 10m/min or light packs at speeds of around 100m/min.

The belt thickness and belt density must be consistent throughout the entire belt length. Variations could result in larger absorption signals and possible false rejects.

Static charges can build up, particularly when the belt is running over plastic skid-plates or plastic-coated rollers. For this reason, the belt should be anti-static, particularly in the case of high-surface friction-style 'sticky' belts. A static discharge could affect both the x-ray detector set and the electronics which process the signal from the x-ray detector set.

A single-pass endless belt design through the x-ray beam is also recommended. The single-pass design also allows for an easy, quick and tool-free full belt removal from the machine, when hygiene or maintenance procedures are taking place (Figure 4.17).

By contrast, an endless double-pass belt arrangement puts twice the thickness of the belt in the path of the x-ray beam, and results in reduced sensitivity.

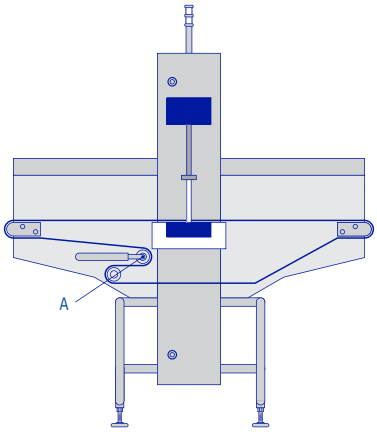

Figure 4.17

In bulk-flow applications, where loose and free-flowing unpackaged product is in direct contact with the belt and/or side-skirted guides, transport-handling materials must comply with FDA regulations and EU Directives. In the EU, the material used must adhere to REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food (this document repeals directives 80/590/EEC and 89/109/EEC).

A Letter of Assurance (and migration test results) should be kept by the machine manufacturer and should be made available to customers on demand. The CE certificate for the machine should also reflect this level of compliance.

4.3.3 Guide Rails

Guide rails should be made of stainless steel and should also be fully adjustable for easy set-up (Figure 4.18). They should have the minimum surface area required to guide the packs through the machine correctly, especially if curtains are being used. Indeed, the use of deep plastic rails can have the effect of increasing x-ray scatter; this leads to increased dose rate at the entry/exit to the machine.

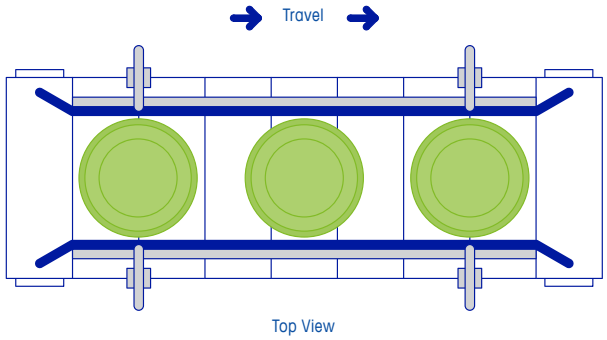

Figure 4.18

4.3.4 Product Transfer

Poor transfers on and off the x-ray conveyor can cause product jams and x-ray imaging issues. Special attention needs to be given to these matters when the end rollers are large or the product is small (Figure 4.19). If the distance (D) between roller centers is more than half the product length, reliable transfer will not be possible. Small non-powered intermediate rollers, or a dead-plate positioned between the two rollers, provide effective solutions for some products.

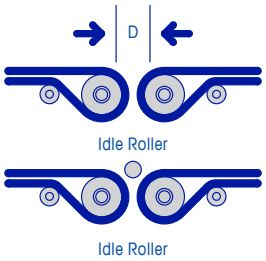

Figure 4.19

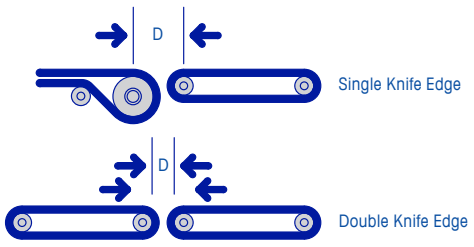

Figure 4.20

Single or double knife edges (Figure 4.20) permit transfer of very small packs, where product registration needs to be maintained. This applies, for example, to rows of confectionery at the outlet of an 'enrober' (a machine which coats ingredients or core products with chocolate).

Sticky products such as raw dough, meat – and bulk loose product such as raisins – are typically transferred by cascade (Figure 4.21). Where a cascade is used, the product should be presented consistently and not in large clumps.

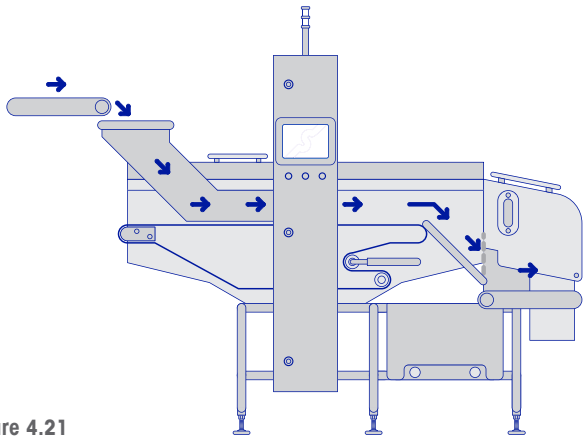

Figure 4.21

For jar and bottle inspection (on horizontal beam systems), an in-line transfer can be difficult, since the packs are unstable and tend not to self-transfer across dead-plates. Unless special handling devices are used for in-line transfers, packs will fall over or lose 'pitching'. A common method of transfer for these containers is a side-to-side transfer from the main conveyor line onto the x-ray conveyor line and back again. This is a basic concept for side transfer.

4.3.5 Transfer Speed

A key feature on x-ray systems is that analysis of the product/package processing (and decision-making) is image-based. Imaging eliminates PEC (Photo-Electric Cell) timings or associated trigger errors, so the gap between the products can be very small (as little as 2mm), depending on the application. The required minimum gap is usually dictated by the conditions needed for effective rejection, rather than effective imaging.

However, on some multi-horizontal beam systems, the beam spread requires that the gap needs to be larger and also consistent; what's more, good spacing helps with positive reject timings (Figure 4.22).

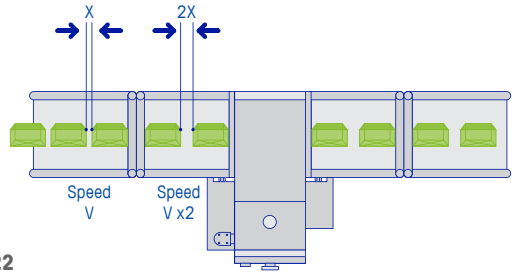

Figure 4.22

4.4 Automatic Reject Systems

A range of different types of reject systems is available. The correct choice depends on a number of factors such as type of environment, belt speed, pack weight and pack size. The x-ray machine acquires a detailed image of each pack at a known belt speed, so it knows the precise location of the center of the pack as it travels along the belt. Rejection is therefore very positive and accurate, with no timing photocells required (unless the pack rate is very high).

4.4.1 Air-Blast Rejects

A blast of air blows the product in the direction of the reject receptacle (Figure 4.23). This type of reject system is ideal for packs up to 500g in weight, and is mainly used on small packs running at high speeds on narrower belt systems. Fitting a controlled variable air-flow reject valve allows settings to be optimized easily.

Timings are set very simply; the reject 'delay' time is the time-gap between detection of a contaminated pack and firing of the air blast that rejects the contaminated pack from the production line. The reject 'duration time' is the duration of the air blast.

Air blast works very well for small to medium-sized packs that are produced in-line very close to each other (i.e. where there is only a small gap between them), since no time is needed for a forward or return stroke. However, a forward or return stroke is required when a pusher reject system is used (see Section 4.4.3). For longer packs which could rotate when the air blast strikes them, a twin parallel-nozzle air blast works better, because this prevents rotation by acting like a wall of air. As most x-ray systems use a PU (Polyurethane) belt, consideration should be given to the natural tack of the belt surface and to any increased stickiness if the belt becomes wet.

Very lightweight packs can become airborne, and there are special designs available to avoid this occurrence, such as a low-level polycarbonate horizontal plate over the belt to keep the product in place between the air blast and receptacle.

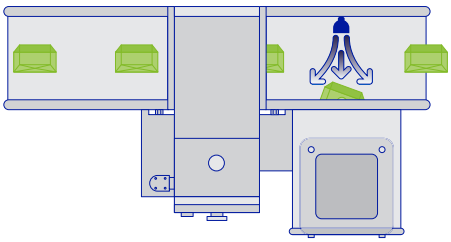

Figure 4.23

4.4.2 Overhead Pusher Rejects

The overhead pusher reject system uses a rod-less cylinder mounted over the conveyor. It's a compact design, since the complete reject mechanism is contained within the machine guard. A standard design will work on packs up to around 5kg in weight, while heavier packs can be rejected by larger, stronger cylinders with special damping arrangements. The rejection is very smooth and positive, and different pusher faces can be used to suit individual products. For example, where flexible pouches are on the production line, scoop shaped like a 'snowplow' can be fitted; this scoops under the edge of the packs so as not to trap them and cause them to burst on the belt (Figure 4.24).

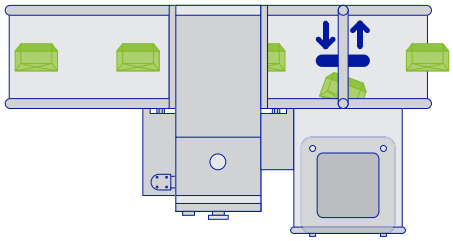

Figure 4.24

4.4.3 Side Punch / Pusher Rejects

To create a 'punch'-based product rejection process, a side-mounted cylinder is normally used for high-speed rejection of medium and heavyweight packs including cans, bottles and glass jars. Since it has a very short stroke, a side-mounted cylinder can quickly push the reject pack off the line and then move back out of the path of the next pack on the line. Typical applications of the side punch include canning lines and glass-in-glass inspection lines (Figure 4.25).

Acting as a pusher, the same mechanism can make a slower and longer stroke for pushing very heavy packs (20kg) at slower speeds and slower pack throughputs. An L-shaped bracket can be fitted to the pusher face, so that no packs get trapped behind the pusher face on the return stroke.

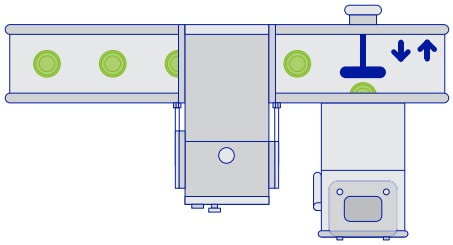

Figure 4.25

4.4.4 Sweep / Diverter Arm

An arm moves at an angle across the belt to divert products into the receptacle (Figure 4.26). This reject is suitable for light to medium-weight, discrete, random, non-oriented products running on a belt which can be, typically, up to 350mm wide. Care needs to be taken that products enter the receptacle correctly, as they usually enter at a diagonal angle.

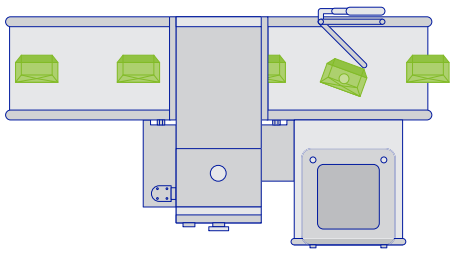

Figure 4.26

4.4.5 Retracting Belt

The conveyor end roller moves backwards to create a gap in the flow, allowing the product to drop through (Figure 4.27). After rejection, the roller moves forward to the closed position. To avoid trapping the product, the roller always moves faster than the belt speed. End rollers can be made as knife edges to ease product transfer on small products. This reject system can be used in multi-lane and bulk-flow applications.

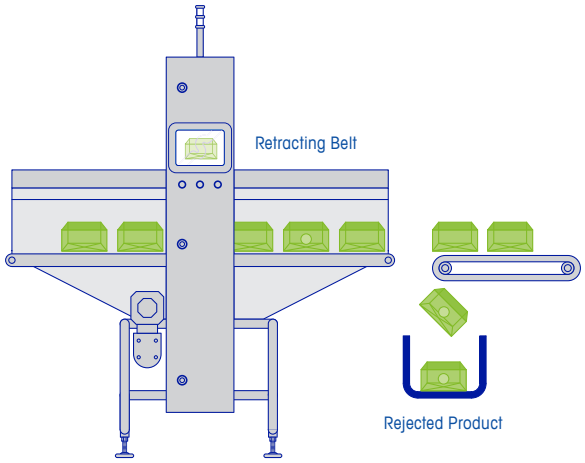

Figure 4.27

4.4.6 Multi-Lane Rejects

In multi-lane applications, a single full belt-width reject system will not guarantee removal of all packs across all lanes, since:

a) The packs may be out of step in each lane. If so, using a retracting belt reject may cause other packs to be disturbed or become trapped in the reject device.
b) Depending on packs in other lanes to push the suspect pack off the belt is not reliable – this occurs if a pusher is used.

In addition, a single reject is likely to remove good product along with contaminated product, and so create a large amount of waste. Since a single conveyor belt (across the width of the machine) can be sub-divided into individual lanes, it's recommended that a separate reject device should be fitted to each lane.

For simple twin-lane applications, two overhead pushers or two air blasts can be centrally mounted between the lanes, and they will independently reject packs outwards to the receptacles. For more than two lanes, reject flaps can be used.

A 'drop-flap' is a metal plate that is angled downwards from the x-ray conveyor to the production-line conveyor. Good product is transferred down (over the plate), but when a defect pack is detected, the plate lifts up or drops down to divert the pack into a receptacle underneath. If the pack will not transfer properly across the metal plate, it can be replaced with a driven conveyor (now normally on the horizontal), which ensures positive transfer through and off the x-ray conveyor.

4.4.7 Bulk-Flow Rejects

In bulk-flow applications, no individual lanes are set up; instead, the x-ray continually acquires an image across the width of the belt.

The inspected bulk-flow product cascades off the end of the x-ray conveyor. If a contaminant is detected in the product flow, the positions of the diodes observing this contaminant (across the width of the belt) are exactly known. So, by sub-dividing the full-width array of diodes in the detector into consecutive banks of diodes, a signal can be given from each bank to a single corresponding reject device in line with where the contaminants will pass. As a result, instead of rejecting a full belt width, rejection is confined to a much smaller amount of product.

The more reject banks there are in the detector, the more reject devices there can be – and hence fewer products are rejected and wasted per reject operation. The actual rejection mechanism for contaminated product can be mechanical scoops or air-blast devices. In a multi-mechanical reject scoop system, the good product cascades over the scoops, but when a reject is detected, the scoop lifts up into the flow and diverts the contaminated product backwards and into a receptacle (see Figure 4.28).

For a multi-air-blast reject system, the nozzles are aimed at an angle towards the cascade of product. They blow contaminated product backwards out of the cascade into a receptacle. Multiple rejects ensure positive rejection and minimum reject waste.

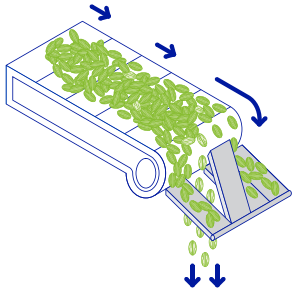

Figure 4.28

4.4.8 Pipeline Reject Valve

For pipeline applications, an automatic reject valve is fitted in-line a short distance after the inspection point. The valve rotates open, before and after the point at which the contaminant is within the flow. It thereby rejects a portion of product which contains the contaminant, and directs it into a reject container. For liquids, slurries and pastes, a simple three-way diverter valve is usually suitable. For denser products like whole muscle, a higher-grade slicing valve will be needed. Timing is very accurate and can be monitored (and controlled) automatically via an encoder or tacho pulse from the pump.

4.5 Reject Receptacles

There are a number of different methods in use for containing the rejected product. These are discussed below.

4.5.1 Tray / Hood / Bin / Chute

These are the simplest and most economical forms of receptacle, and are mounted on the x-ray system at the point of rejection.

Tray

A tray is a simple three-sided holding table with no cover, where rejected packs enter and are contained.

Hood

A hood is a box-shaped structure with openings on one side and in the base. The rejected pack enters through the side opening before dropping down and out through the base. The hood acts as a funnel to direct rejects down to a re-work area – or into a receptacle, such as a stainless steel tote bin.

Bin

A bin is a box-shaped structure. It has an opening on one side to admit rejected products – and a side access door near the base, for removal of rejected products. Good practice is to have drainage holes in the base for easy cleaning processes. It's recommended that the door is lockable, so that only designated personnel can remove rejected packs.

Chute

A chute is a long, narrow and horizontal bin, usually angled downwards away from the machine. Instead of rejected packs dropping into the base of the bin (with the risk of damage), the packs slide down to the bottom of the chute. A chute is typically used for fragile containers, or for containers that require detailed inspection.

4.5.2 Declined Roller-Track Reject Chute

A declined roller-track reject chute is a reject chute with rollers in the base. Reject packs are easily and smoothly transferred via the rollers to the bottom of the receptacle. Since no damage is caused to the product on rejection, this is ideal for use on re-workable high-value products. It's also appropriate for products that may have a missing or damaged component. These packs can be fixed (or components replaced) and can be re-inspected. Again, drainage slots in the base, a viewing panel, and a lockable access hatch are good design practice.

4.5.3 Parallel Reject Conveyor

A parallel reject conveyor runs parallel to the x-ray system. It's used in applications involving:

a) A large number of rejects (so a large holding area is required for rejected packs)
b) Packs that could easily break on being rejected into a bin
c) Packs that can be reworked and automatically taken back upstream for re-processing

4.6 Typical Reject Problems

A correctly specified machine should be fool-proof and capable of rejecting all contaminated packs under all circumstances, no matter how frequent the occurrence or the location of the contaminant inside the pack.

The following are common application problems which should be taken into consideration when specifying an x-ray inspection system:

- Reject not suitable for the application.
- System not capable of removing consecutive contaminated packs.
- Failure of the reject due to low air pressure/volume, pipe blockage or solenoid failure.
- Downstream product backing up to and through the x-ray system.
- Conveyor speed changed without changing reject timings.
- Product spacing/pitching and reject not compatible.

One of the benefits of a single source of responsibility for conveyor, reject and x-ray inspection systems is that all these issues can be addressed at the design stage.

4.7 Satisfying Retailer and Food Industry Requirements

Simple additional control devices can be included within the x-ray system to ensure a reject device is operating properly, i.e. that contaminated packs are accurately rejected and the x-ray detection system is operating in a failsafe mode. Implementation of the following design requirements generally represents good practice and will satisfy most brand, retailer and food-industry requirements:

- An automatic reject system to effectively remove suspect packs from the line.
- A lockable receptacle which is located at the nearest point to the reject system to receive suspect packs. Only authorized and trained personnel will have access. If product is rejected into an open container (or is readily accessible), it could easily be returned to production in error. Rejection into lockable reject receptacles prevents this from occurring.
- A full enclosure between the x-ray beam (point of inspection) and the reject receptacle, to prevent personnel removing a pack from this area (which may be contaminated).
- An audible and visual alarm display of system status – e.g. product has been rejected.
- Identification of packs which have become stationary in the x-ray beam. If packs back up into the x-ray beam and the beam is blocked for an unacceptable amount of time, the belt and x-rays will stop.
- Air-pressure monitoring switch. If the air pressure to the reject system drops below a pre-set acceptable level, a fault signal is sent to the control system.
- A reject confirmation photocell mounted across the entrance to the receptacle to detect each pack that enters the bin. When the reject system is activated, failure to trigger this photocell within a set period of time indicates that the rejected pack didn't enter the receptacle. A fault signal is sent to the control system.
- A 'bin full' warning photocell which is located typically one third of the depth of the bin below the level of the conveyor belt surface. If too many packs are in the bin, the photocell is blocked and it sends a fault signal to the control system.
- An automatic belt-stop failsafe system in response to the following conditions:
  – Reject confirmation failure
  – Bin full warning
  – Low air pressure
  – X-ray inspection fault

It shouldn't be possible to restart the x-ray machine without a security password or a key switch held by a nominated person. Suitable line logic should be installed so that the in-feed conveyor is stopped if packs are building back on the takeaway conveyor downstream from the x-ray system. When this system is in place, the x-ray system continues to run and its conveyor is always able to unload inspected packs.

4.8 References

Links to various sources and types of information are included below for reference:

3-A standards organization

http://www.3-a.org

EHEDG

http://www.ehedg.org

NSF International – Independent US organization dedicated to developing standards on Food Equipment, Ref. NSI/NSF 2 –1996

http://www.nsf.org

European Food Safety Authority

http://www.efsa.europa.eu

Consumer Goods Forum

http://www.consumergoodsforum.com

GFSI

http://www.globalfoodsafety.com

IFS Audit Portal

http://www.ifs-certification.com

British Retail Consortium

http://www.brc.org.uk

Dutch HACCP

http://www.foodsafetymanagement.info

European Food Safety Inspection Service (UK)

http://www.saiglobal.com

European Consumer Response

http://www.ecr-all.org

SQF

http://www.SQFI.com

Key Design Features of an X-ray System

A good x-ray inspection system improves production quality without reducing production efficiency.

5

Key Design Features of an X-ray System

Moreover, a good x-ray inspection system is:

- Reliable.
- Easy to clean and maintain.
- Simple to set up.
- Time-saving.
- Cost-saving.
- A valuable and vital element within HACCP compliance procedures.

When manufacturers understand and appreciate how each element of system design affects detection rates and day-to-day production routines, it helps them to choose a system that's right for their operation, while also obtaining the results they require.

Selecting a reliable x-ray system is a crucially-important step towards minimizing or eliminating the occurrence of product contamination. However, despite the widespread use of x-ray systems, there are few guidelines to assist users in evaluating special features of x-ray systems or to help them compare the capabilities of different machines.

This chapter provides practical guidance on the design features that make a measurable difference to the success of an x-ray inspection program. This chapter also considers the factors of prime importance for users with long-term experience of running effective contamination detection programs.

The key factors determining the success or failure of the overall contamination detection program are principally:

- Drift in sensitivity.
- Erratic detection or false rejects.
- Complexity of set-up.
- Difficulties with maintenance.
- Machine hygiene.

Production personnel can become frustrated when x-ray inspection systems appear to operate inconsistently.

People will lose confidence in a machine that rejects product which is subsequently shown to be perfectly good, or they will

lose patience with a machine that requires constant attention in order to maintain the required sensitivity standard. An x-ray system that constantly achieves the performance levels initially set for it (with minimum human intervention) will win the confidence of line operators and management, as well as provide the best long-term protection. Production-line sensitivity and efficiency are the measures which take all these factors into account.

5.1 Health and Safety by Design

The system design must comply with local rules, as well as with regulations on the use of ionizing radiation for the country in which the machine is being used. Tunnel guards and end curtains are most commonly used to retain x-ray emissions, but their presence means that the system is also accessible to operators. However, well-designed systems will ensure safe and easy access, so that there is no need for the operator to reach into the machine.

It's also important to be aware of the regulations for the country in which the machine is to be used.

In modern factories, it's now standard procedure for the entire line to have a safety system. ISO 13849-1 Category 3 safety systems are standard on all well-designed machines and will fully integrate with the manufacturer's safety circuit – in fact these features should be standard on any x-ray system.

Radiation regulations state that a highly-visible lamp stack (with a label reading 'x-rays ON' mounted on top of the beacon) should be clearly visible from 360 degrees around the machine. The lamp stack is monitored and, if it fails, x-rays can't operate. These days, LED lamps are becoming the preferred option, since these are more durable than glass lamps.

5.2 Cabinet Design

The x-ray cabinet should be made entirely from stainless steel, and ideally should be sealed to a minimum IP65 rating. A higher-rated sealing (IP69) should be chosen for harsh wash-down environments – typically in meat, fish and poultry applications.

Many x-ray systems include air-conditioning or heat exchangers as standard – though modern x-ray systems have been designed so that they require neither of these features. Machines operate at a safe temperature and require no additional heat extraction, cooling or additional heating mechanisms.

Many x-ray systems feature air-conditioning or heat exchangers to keep the internal electronics at a safe operating temperature within a sealed cabinet design. This is the preferred option over a basic in-take and out-take cooling fan design, in which the cabinet interior is exposed to the factory atmosphere and temperature. Should the cabinet be open, the IP rating would be below IP65; with the cabinet closed, some manufacturers offer high IP ratings on air-conditioning units. Air-conditioning is more convenient than water-cooling, since plant water is not needed or wasted.

Good cabinet design will also incorporate a temperature monitoring system to alert the operator and protect the system in the event of the cabinet overheating.

A cabinet heat exchanger provides an adequate level of cooling for most environments (including chilled or sub-zero atmospheres), while also ensuring a satisfactory IP rating. This is because the cabinet is, effectively, an enclosed unit suitable for harsh wash-down environments.

Internal electronics should include a mains current suppressor, a filter and a UPS (Uninterruptable Power Supply) for non-embedded operating systems. In the event of a power failure, a UPS performs a safe shutdown of the system, saving all settings on the operating system.

5.3 Conveyor Design

The conveyor belt must be simple and easy to remove without the use of tools; in addition, it should incorporate a simple quick-release/tensioning roller device, plus tracking should be easily adjustable. On wide-belt applications (typically over 800mm) or on very wet or greasy applications, automatic belt tracking should be considered. Problems with belts becoming misaligned can cause substantial downtime.

For bulk-flow applications, troughed belts or side-skirted belts can be used; they retain product on the belt, minimize spillage and improve the transport of product at a constant depth.

5.4 Hygienic Design

All systems should be designed with due consideration for their operating environment and the types of cleaning regimes likely to be encountered. Hygienic design principles should be applied to the complete system and relevant considerations should include:

- Elimination of cavities/bacterial traps.
- Sealing of all hollow sections.
- Avoidance of ledges and horizontal surfaces.
- Use of open-design, continuous welded frames for easy access and cleaning.
- Hygienic management of electrical cables, trunking and pneumatic services.
- Angled or sloping surfaces.
- Drainage slots in catch trays.
- Easy strip-down of belts and components (wherever possible), to ensure cleaning is complete and thorough.

Good design will greatly help with on-site HACCP compliance. There are a number of authorities that offer advice to both machine providers and end users on this topic; for example, 3A, AMI, EHEDG and NSF machine design standards and their associated approvals are now highly respected.

Reputable x-ray system providers follow industry guidance for supply of equipment to the food and pharmaceutical sectors, with stamped-type approval. EHEDG, in particular, offers

guidance on the hygienic design of open and closed processing equipment, paying particular attention to the design of valves, O-rings/pipe, couplings/aseptic manifolds, the sealing of shafts, the welding and construction of surfaces and joints, plus drainable design.

Well-designed x-ray pipeline systems incorporate Clean-In-Place (CIP) procedures. CIP provides for a flush-out of the pipe-work with hot cleaning fluid at the end of a production run, with no need to disassemble the manifold or disconnect the pipe-work.

For sterile applications, an aseptic manifold is available. This design incorporates a set of double O-ring seals on either side of the x-ray window section, where it connects to the stainless-steel manifold. The design allows for CIP, and steam can be passed through the system to kill any micro-organisms present, without the need to dismantle the manifold assembly.

5.5 Choice of X-ray Tube

Manufacturers of x-ray systems should offer a choice of x-ray tubes to suit individual applications. A glass-window x-ray tube is the most common type because its penetration abilities suit a wide variety of applications.

When the product to be inspected is of low density and small in depth (typically less than 30mm), a beryllium-window x-ray tube can be used instead of glass. This lower-energy tube creates softer x-rays, which give better contrast and better detection levels for medium-density contaminants such as glass, mineral stone and calcified bone. It's particularly suitable for bulk-flow applications, small thin-pack applications and product-in-seal inspection applications, plus it offers improved detection of bone in poultry.

5.6 X-ray Detector

Various diode sizes create different detector arrays – and the criteria for detector selection (plus how a detector affects the sensitivity of detection) are discussed in detail in Chapter 7. However, by way of a brief summary of this subject, regular x-ray systems contain one detector which comprises individual elements ('diodes'). These diodes convert the level of detected x-ray dose into an electrical signal, which is scanned by the system's electronics. A 'line' of data, representing each diode in turn, is passed to the on-board control system for analysis.

There are many configurations of detector from many different manufacturers – and typically, diode sizes range between 0.4mm and 1.6mm pitch (the distance from center to center of the photo diodes). It's popularly thought that, no matter what the application, smaller diodes give better sensitivity, but this is not the case.

As a comparison, a 0.8mm diode will have four times the surface area of a 0.4mm diode. Therefore the 0.4mm detector diode would need to receive four times as much x-ray energy to create an image quality comparable to the 0.8mm diode. In effect, resolution improves as diode size decreases, but throughput or conveyor speed must slow down to maintain image quality.

Modular detector design allows a complete array of diodes to be made from smaller 'banks' of diodes. This improves detector efficiency and can aid future maintenance or repair. In addition, modern software techniques ensure that unwanted electrical noise can be filtered out (especially at high line speeds), so as to produce a clean and more accurate signal from the detector. The end result is a better-quality x-ray image.

5.7 User-Friendly Interface

The system must be simple and easy to use. Modern x-ray systems have full-color LED touch-screen displays with intuitive software that allows set-up in minutes and reduces operator error. Remote displays can be added to ensure even better visibility; these remote displays also allow for operation from upstream or downstream. Different levels of password-protected user access are now a standard protocol, reducing possible errors or unnecessary faults.

For ease of use, the operating system should be available in multiple languages so that operators can easily switch to their language of choice – and provided training is sufficient to meet HACCP obligations, a more user-friendly system allows operators to gain the many benefits of an x-ray inspection system. Overall Equipment Effectiveness (OEE) is a key measure of performance, and the information required to monitor OEE is readily available from a good x-ray inspection system.

5.8 Variable Scan Speed

Advanced x-ray systems offer the ability to change scanning, relative to the line speed. Usually a signal is sent to the x-ray via an encoder, which informs the x-ray system at what speed the line is running. If the line speed increases or decreases, the x-ray scan speed will do so too; it will also change associated reject timings to suit the production-line speed. It's extremely important that the image proportions and brightness are maintained at varying scan speeds, particularly for high-speed bottling and canning lines, and in any application where pack spacing must be maintained.

5.9 Adaptive Filtering Technology

For products packed in containers with dense edges, the high-absorption dark areas can be filtered out so that detection is optimized elsewhere in the image. Since physical tolerances of containers can vary, the use of fixed-width filters might result in a thinner side wall allowing a contaminant to pass undetected, since it would be hidden in the filter. In addition, a thicker side wall would emerge outside the filter into the inspected area and cause a false reject.

Glass container thicknesses can vary by 20%, and dynamic filtering overcomes this issue by changing to suit the individual profile of each pack, optimizing sensitivity and minimizing false rejects.

5.10 Auto Calibration and Monitoring

Well-designed operating systems continually monitor signals from the x-ray generator and detector, to check for any drift in performance. A full calibration is only required every 28 days (see Calibration Software in Section 6.3).

It's good practice to calibrate as often as possible; however, during the calibration of an x-ray pipeline system, there must be no product in the pipe or in the path of the x-ray beam. This can be difficult to achieve because the pipe will be full of product, and it may not be possible to clean or remove the manifold during production. A good design allows for automatic removal of the x-ray generator and detector system from the manifold. After calibration, the equipment can be returned to the running position – and the overall benefit is saved time and reduced product waste.

When undertaking regular Quality Assurance checks, it can be difficult to insert a calibrated test piece into a pipe that's working at pressures of 5 bar / 70psi or more. In addition, it's easy to lose the test piece if the reject timing is incorrect or if the machine is incorrectly set up. However, the problem can be overcome via an external automatic test, which simulates the test piece in the product. External automatic tests increase efficiency, reduce labor costs and avoid potential contamination during testing.

5.11 Information Storage

Many x-ray systems are PC-based, and record a great deal of useful information – so the PC should be specified to provide sufficient processing at all times. Features such as USB and Ethernet ports allow immediate access to statistical data and the reject image library; this data can be used for production and quality reporting or as a traceability tool. Again, this can be helpful with HACCP compliance, and is discussed in greater detail in Chapter 21.

5.12 Self-Diagnostics and Remote Diagnostics

Well-designed x-ray systems will have built-in self-monitoring software which continually checks all the components, as well as the operation of the machine. It can flag up a potential problem in advance, so as to provide an early warning system, plus a field-based service engineer can remotely dial into the machine via a manufacturer's Ethernet network, in order to fix the fault online or prepare parts and relevant personnel for a site visit.

5.13 Failsafe System Design

As mentioned in Section 5.1, a lamp stack (to indicate the status of the x-ray system) must be clearly visible from 360 degrees around the machine (Figure 5.1). The lamp stack options indicate that:

- X-rays are on/off.
- The system is in fault mode.
- Power is passing through the machine.
- The system is healthy.

The lamp stack also alerts operators that a PVR (Performance Verification Routine) is required (see Chapter 16) and indicates the activation of any failsafe feature discussed in Chapter 4 i.e. reject confirmation, bin-full warning and low air pressure. An audible alarm is usually activated at the same time.

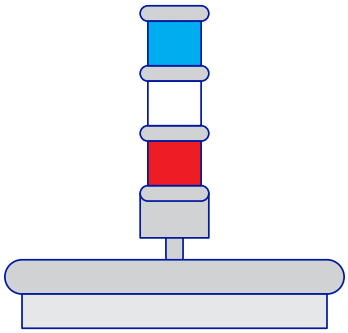

Figure 5.1

5.14 References

Links to various sources and types of information are included below for reference:

3-A Standards Organization

http://www.3-a.org

EHEDG

http://www.ehedg.org

NSF International – Independent US organization dedicated to developing standards on Food Equipment, Ref. NSI/NSF 2 –1996

http://www.nsf.org

Codex CAC/RCP-1 1969 Rev 3-1997, Amd. (1999) Recommended International Code of practice: General principles of food hygiene including Annex on HACCP system.

http://www.fao.org/docrep/w8088e/w8088e04.htm

EN ISO 9001:2000 and ISO 22000:2005 (Sept.1, 2005) Food safety and quality management systems – IDF International Dairy Federation

http://www.fil-idf.org

American Meat Institute (AMI)

http://www.meatami.com/

Key Factors Affecting Sensitivity

If the detection sensitivity is set too low, bad product can slip through; if the sensitivity is set too high, then good product is falsely rejected. However, understanding how various factors (such as x-ray source, diode size, product size and product composition) affect sensitivity helps manufacturers to specify a system that will deliver optimum performance.

Manufacturers who combine this knowledge with an understanding of effective system set-up and testing, will be able to choose a machine that's fit for purpose; they can install a system that will meet the required standards and will perform as expected in a live production environment.

Factors affecting sensitivity can be divided into three categories:

1. Product characteristics and application
2. Types of packaging
3. System design

Any changes to physical parameters within each of these groups will affect how well a system works. Parameter changes can increase, decrease or negate possible changes in the level of detection.

6.1 Product Characteristics and Application

X-ray inspection works by looking for product contaminants that have a higher absorption than the product itself. The amount of x-ray absorption in typical contaminants is discussed in greater detail in Section 1.6.

6.1.1 Factors that Affect Absorption

The main factors that affect absorption are:

- Product density and product depth
- Chemical composition (atomic mass number)
- Product texture or uniformity

Product Density and Product Depth

Absorption of x-rays is proportional to the depth and the density of the product they travel through. When a contaminant is present, it absorbs more x-rays than the surrounding product, and appears as a localized increase in absorption. The magnitude or 'contrast' of that localized increase is proportional to the contaminant's thickness and the difference in absorption rates between the contaminant and the product (see Figure 6.1). In other words, the same contaminant will show more contrast in a less dense loaf of bread than it would in a denser piece of cheese. So, when inspecting bread, sensitivity is better than when inspecting cheese.

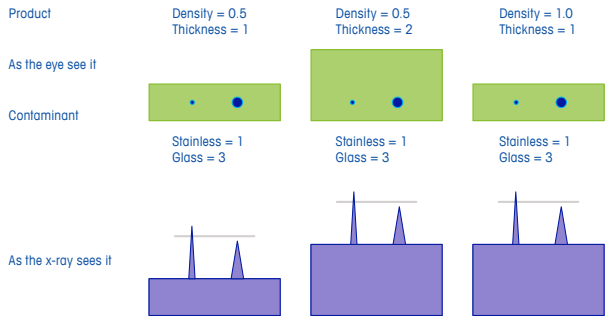

Figure 6.1

As the density and thickness of the product increases, more x-ray energy is required to penetrate or pass through it. Increasing the x-ray penetration power (kV) reduces the contrast created by the contaminant – which, in turn, reduces sensitivity. As the product depth increases, more x-ray energy is required to penetrate it; in addition, system sensitivity decreases.

Chemical Composition (Atomic Mass Number)

The chemical composition of the product and the contaminant (or test card) will also affect overall sensitivity. Food products typically contain chemical elements with atomic mass numbers of 16 (oxygen) and under. Given that food products are made up of low atomic mass-number elements, the x-ray absorption of food is proportional to product density and depth.

Contaminants such as glass and mineral stone often contain trace levels of some very high atomic mass elements. These high atomic-number elements act as 'multipliers' of x-ray absorption. For this reason, manufacturers of x-ray-detectable consumables (scrapers, plasters, 'doped' plastics) have developed the addition of heavyweight elements – because changing their composition in this way ensures that non-x-ray-detectable products become detectable.

Soda-lime glass (also called 'soda-lime-silica glass') is the most prevalent type of glass used for glass containers, e.g. bottles and jars. It's, therefore, the most common glass used for x-ray test cards. Soda-lime glass may contain trace levels of high atomic mass-number elements – and their presence increases the absorption of x-ray energy by as much as 400%. However, these high-absorption glass materials may be nothing like the glass used on the actual production line. It's, therefore, important to use a consistent glass test sample when comparing capabilities between various x-ray systems.

Stones occur naturally, so they are highly variable and may also contain some high-atomic-mass-number trace elements. Since x-ray detectability (size) depends on the contaminant's absorption characteristics, it's difficult to predict stone detection, so it's strongly recommended that detection capabilities are evaluated using stones typically found in the particular product, since they will give a realistic picture of what's detectable.

Large changes in salt content (sodium chloride) also affect the level of x-ray absorption and system sensitivity. This is particularly applicable when an x-ray machine is also being used as a mass measurement system (see Section 8.5). Large variations in salt content will affect the repeatability of mass measurements using an x-ray system; however, since salt levels in many modern food products are very low and carefully controlled, this is not usually an issue.

Product Texture or Uniformity

Homogenous packs are the easiest type of product to inspect, since the constant pack signal means that small absorption changes can be readily detected. However, many food and pharmaceutical packs comprise areas of varying absorption caused by variable product amounts, gaps or air pockets (see Figure 6.2).

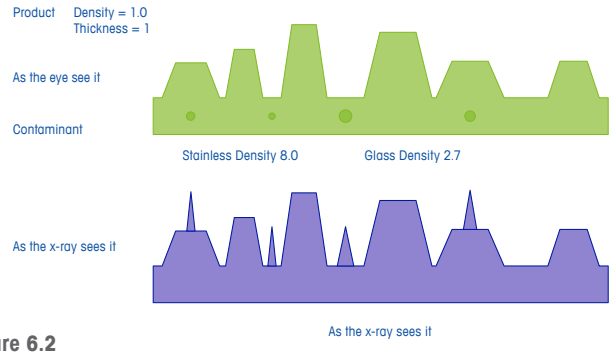

Figure 6.2

Radial contrast image analysis tools are often combined with thresholding tools – and the resultant tool can cope with variations in the x-ray gray-scale image. These 'busy' images (e.g. a bag of potatoes) are inspected at pixel level, rather than as one complete image – and the software looks for contrast change on a local level. This allows for overall improved sensitivity and probability of detection. Good practice for test procedures is discussed in Chapter 16.

6.1.2 Factors That Could Affect Absorption

Contaminants / Test Cards Outside or Embedded in the Product

If the contaminant is outside the product, rather than embedded in the product, there is no product displacement, so contaminant absorption is added to product absorption. In effect, overall absorption (and hence sensitivity) is very slightly improved when there is a large difference between the contaminant density and the product density.

Less dense contaminants such as aluminum, glass, mineral stone, and calcified bone would exhibit greater difference outside the product, as compared to when embedded in the product. Figure 6.3 graphically demonstrates this relationship, showing that the stainless steel signal is about the same, while the glass signal reduces by about 40% when the glass contaminant is embedded in the product.

Plastic creates a small signal reduction when placed outside the product, because the depth (product plus contaminant) is increased. When plastic contaminant is embedded in the product, there is no change. This is because the plastic, and the product it displaces, both have an SG of 1.0. When embedded, the plastic contaminant becomes invisible to x-rays and is undetectable.

Figure 6.3

Position of a Contaminant in the Path of the X-ray Beam

When placing a contaminant (or test card) closer to the x-ray source or closer to the detector, this has an effect on detection levels. When the contaminant is near to the source, the effective area projected over the detector (its x-ray 'shadow') is enlarged or magnified (see Figure 6.4). However, the magnification effect also means that the image of the contaminant is slightly blurred because of loss of sharpness at its edges.

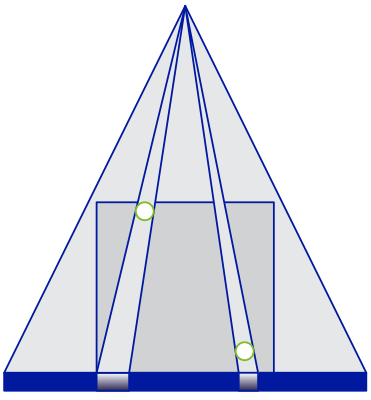

Figure 6.4

When the contaminant (or test card) is located near to the detector, the image of the contaminant becomes sharper; this is easier to detect using radial image analysis tools.

Location of the contaminant is relevant for larger-depth packages; however its impact will also depend on the detector diode size and the (radial image) analysis techniques utilized. With modern image analysis tools, the magnification effect can improve the detectability of contaminants in very deep products, since the blurred edges can be ignored.

Since so many variables (product, packaging, and machine) affect the final result, it's difficult to define a single optimum test position (the most challenging position) that would cover all applications.

6.1.3 Factors That Do Not Affect Absorption

Temperature

Variations in temperature have no effect on sensitivity of detection. On lines where product temperatures vary, the x-ray system remains stable and maintains a high tolerance on achievable levels of detection.

Traditional inspection systems are affected by changes in product temperature, so they generate many false rejects. However, an x-ray system generates the absolute minimum of false rejects, which offers increased line efficiencies.

Moisture Content

Variations in moisture content have little or no effect on sensitivity of detection. By contrast, this is a problem that traditional inspection systems can suffer from, since they typically work on the principles of conductivity.

6.2 Types of Packaging

The most common use for x-ray systems in the food industry is inspection for metal contaminants (particularly stainless steel – typically, 90% of all metal in a food factory is stainless steel). X-ray systems also look for other contaminants in product contained within foil or metalized film packaging.

Foil trays can have very dense edges that reduce overall sensitivity, so a simple mask or box filter can be applied to the pack. This will have the effect of removing these dark edges and optimizing performance. Similarly, metal clips (used on wrapped sausages or plastic tubular packaging) can be ignored in the image, but the remaining internal area of the pack is still fully inspected.

Metal cans and glass jars are more challenging, since parts of these containers will always be present in the inspected image. Modern special adaptive masking and inspection routines offer unsurpassed detection by dynamically adjusting to each individual pack.

Contaminant	Typical Detection sizes in Various Packaging Types (Sphere Diameters)			
	Plastic or Paper	Metalized Film or Foil	Metal Can	Glass Jar
Metal*	0.8mm	0.8mm	1.2mm	1.2mm
Aluminum	2.0mm	2.0mm	2.5mm	2.5mm
Glass	2.0mm	2.0mm	3.0mm	3.0mm
Stone	2.0mm	2.0mm	3.0mm	3.0mm
Bone	3.5mm	3.5mm	5.0mm	5.0mm
Dense Plastic	3.5mm	3.5mm	5.0mm	5.0mm

*Ferrous,Non-Ferrous and Stainless Steel

Table 6.1

It can be seen in Table 6.1 that even in a dense glass jar or can, 1.2mm stainless steel detection is possible. The figures shown are only general, and will be dependent on the variables previously discussed. Some x-ray system providers claim excellent detection levels in steel, but this is usually achieved in controlled test conditions, and should be considered in that context only.

6.3 System Design

Focal Length

Focal length is not generally a problem, since it's the depth and density of product in the beam that makes the real difference. This is because power settings on the machine can be changed as required. For example, a higher power is used on a larger beam for a larger pack; the penetration may be adequate, but since there's a greater thickness of product to inspect, sensitivity is reduced.

Type of Tube – Glass or Beryllium Available

Depending on the application, different x-ray tubes can be selected to optimize the sensitivity of detection and overall performance (see Section 5.5).

Detector Diode Size

The ideal diode size for a detector is the subject of many technical discussions; various diode sizes are available, and they are suitable for different types of detection. Traditionally, it's been said that, no matter what the application, smaller diodes provide better sensitivity – but this is not the case.

Another popular myth is that it's possible to detect contaminants equal in size to, or larger than, the detector diode – but with today's advanced image analysis capabilities, this is no longer an accurate statement either.

Competent x-ray manufacturers now offer a range of x-ray generators with variable current (mA) and voltage (kV) settings, as well as different pitch detectors. The detector and generator are then matched to the inspection application. In this way, users can achieve the optimum configuration of detector diode size and product penetration power for a given production conveyor speed.

For a full discussion on diodes, see Chapter 7.

Mechanical Effects

If the sensitivity tolerances are set very tight, environment vibration (mostly false rejects on the line) can cause problems, so isolation is recommended in these areas. A dirty belt can affect the sensitivity of detection, since it's part of the image and adds to the overall absorption measured. Good practice is to keep belts free of sticky product, labels and debris.

Belt speed affects the sensitivity of detection. X-rays can inspect at speeds of around 100m/min, though the faster a pack passes through the beam, the lower the image quality becomes – and this can affect sensitivity. Therefore it's important that the belt doesn't run faster than it needs to (which is part of the selection criteria for good installation).

Calibration Software

Good x-ray systems will have a continuous monitoring system, which checks the reading from the detector and normalizes or re-zeros the system when there is a space between packs on the belt. This ensures that any drift in sensitivity of detection is continuously minimized. Well-designed x-ray systems will only need a full calibration every 28 days or so, while older x-ray machines (10 years or more) need calibrating every four hours. If calibration is required for any reason, the diagnostics on the machine will raise this matter immediately.

Selecting the Right Diode Size for Your Product

Market-leading x-ray manufacturers offer different-pitch x-ray detectors to suit individual applications and likely contaminants. Diode size is a subject of much debate, and this chapter discusses the various diode sizes available and their suitability for different types of detection challenges. It explains that diode size alone is not the only factor that impacts on detection levels and several other factors need to be considered.

7.1 What are Diodes?

An x-ray detector is to x-ray as a camera is to light – i.e. a way of capturing x-ray energy and converting it into an image form that can be processed by electronics. Regular x-ray systems contain one detector, which consists of individual elements called 'diodes' that convert the level of detected x-ray dose into an electrical signal. Chapter 1 discusses the basics of x-ray inspection in more detail.

This signal is scanned by the system's electronics – and a 'line' of data, representing each diode in turn, is passed to the on-board computer. The scanning process is similar to a fax machine or document/ picture scanner, which also scans a line of data via photo-diodes.

In the case of a fax:

- The paper simulates a conveyor.
- The internal light source of the fax scanner is similar to the x-ray source.
- The print on the paper can be thought of as 'product density'.

As the paper is fed through the fax machine, the print is scanned in a similar manner to the product on the conveyor being scanned. With a detector diode size of 0.8mm, a new line of image data will be acquired for every 0.8mm of product movement in the direction of flow. Individual lines build up sequentially and are stacked into a matrix of pixels, to form the overall image of the pack.

Once the data is compressed and corrected, all the pixels will have a value in the range 0 (black) through to 255 (white). Typically, the product will be represented in the gray level range of 50 to 200. Once the entire image of the pack is acquired, the software detection tools examine it for anomalies (see section 1.7).

Various diode pitches 'pixel sizes' are available to suit a wide range of different products and likely contaminants. They affect the resolution of contamination detection by giving a different image grid or pixel size.

Diode sizes used for food and pharmaceutical applications

typically range between 0.2mm and 1.6mm pitch (the distance from center to center of the diodes). There is widespread belief that, no matter what the application, smaller diodes automatically give better sensitivity, but this is an over-simplification that ignores other factors affecting sensitivity of detection.

7.2 Factors Affecting Detection Sensitivity

A number of factors affect detection sensitivity such as the product itself, the contaminant material, and other factors such as line speed. Each factor is discussed in more detail below. Chapter 6 of this guide offers additional details of common factors that affect sensitivity in x-ray inspection systems.

7.2.1 Spatial Resolution

Spatial resolution refers to the number of pixels utilized in the construction of a digital image. Just like a television, images with a higher spatial resolution are composed with a greater number of pixels than those of lower spatial resolution, resulting in a better quality image.

As well as creating the 'slice size' (as in a loaf of bread), diode size also determines spatial resolution. For example, the smaller the diode, the higher the spatial resolution, and the greater the probability of a contaminant completely covering a diode and providing a maximum detection level.

However, smaller diodes require higher x-ray dosage to maintain image quality. For this reason, there's often a trade-off in this area, since higher-dose x-ray sets:

- Cost more.
- Pass more x-rays through the product.
- Have a greater Total Cost of Ownership (TCO), since they consume more energy (see Chapter 18 for a full explanation of TCO).
- Require more frequent replacement of x-ray tubes.

The most common diode sizes used in the food and pharmaceutical industries are 0.4mm and 0.8mm. As a comparison, a 0.8mm diode will have four times the surface area of a 0.4mm diode – 0.64mm² compared to 0.16mm². So, in order to create an image of similar quality, a 0.4mm detector diode would need to receive four times as much x-ray dose level from the detector as a 0.8mm diode.

Furthermore, in order to maintain the same conveyor speed and product throughput as with a 0.8mm diode, it's necessary to double the detector scanning rate when using a 0.4mm diode. Doubling the scanning rate halves the resulting signal level, so a 0.4mm diode may receive only one eighth of the signal of a 0.8mm diode.

In effect, therefore, spatial resolution improves as diode size decreases, but throughput or conveyor speed must slow down to maintain image quality; alternatively, the scanning rate must rise, reducing both the exposure time and the resultant x-ray dose (and signal output) from the detector array.

7.2.2 Image Creation and Contamination Inspection

With x-ray systems, the general rule is: the slower the line speed the higher the image quality, and therefore the better the detection sensitivity. For higher line speeds, this factor can be compensated for by increasing the x-ray power. Image creation and contamination inspection are discussed in detail in section 1.7.

7.2.3 Position of a Contaminant in the Path of the X-ray Beam

Detection levels are affected, to a small extent, by placing a contaminant closer to the x-ray source or closer to the detector. When the contaminant is near the source (x-ray tube), the effective area projected over the detector is enlarged or magnified.

However, the magnification effect also means that the image of the contaminant is slightly blurred through loss of sharpness at its edges. When a contaminant is located near the detector, the image of the contaminant becomes sharper, and is easier to detect. Chapter 6 explains the relevance of the contaminant's position in greater depth.

7.3 Projection Effect is the Geometric Distortion Which Arises from a Non-linear Source

Using a small diode to inspect larger objects can prove counter-productive, especially if the contaminant is far away. This is because a projected shadow will result in an image that's blurred round the edges.

For example, take a 0.8mm diode; to completely cover a single diode and create 'maximum' signal, a 0.8mm square metal item would be needed.

In reality, such accurate positioning would not exist in a product. Therefore, it's necessary to consider the 'worst-case scenario', when a 0.8mm cube actually falls between two diodes, covering only half each.

It might be expected that half the signal would be produced for each diode, compared to the cube being directly over a single diode, but this is not the case. The reason is that, at the point at which x-rays are produced in the tube, the x-rays emanate from a 'focal spot' of around 1mm in size. To give maximum sharpness, the spot from which x-rays emerge should be infinitely small.

To use another photographic analogy, a pinhole camera will give a sharper image for a small pinhole than for a larger one – so, by comparison, x-rays falling on the diode from the metal cube will have a degree of 'geometric unsharpness'. This, in simple terms, makes the contaminant produce a shadow larger than the item itself, thereby covering more than a half of each diode.

This effect also reduces the contrast of the contaminant, because it's effectively 'de-focused'. Contaminant samples used during testing are usually spheres, since they are not orientation-dependent, as would be the case for a cube. Therefore, a 0.8mm sphere would, in practice, cover less than the full surface of a single diode.

Spatial resolution is important, but basic contrast is crucial too. Without radiographic contrast, contamination detection would be impossible, whether the diode was 0.2mm or 0.8mm.

7.4 Radiographic Contrast

As explained previously, the smaller the diode, the higher the spatial resolution. However, smaller diodes produce less product signal, due to the reduced 'light collection' area – so more x-ray dose must be used, or the signal-to-noise ratio becomes a problem.

7.5 Signal-to-Noise Ratio

Signal-to-noise ratio is a measure of signal strength, relative to background noise. All electrical devices create a level of background noise – so, for example, when you place a needle on a record, using an old-fashioned record player, popping, clicking and hissing can be heard as the needle travels along the groove.

Similarly, there's a degree of inherent background noise in an x-ray detector, even before the x-rays are switched on. However, it's important to keep the noise in the signal as low as possible, in order to produce a better-quality x-ray image.

The more signal left after the x-rays have been attenuated during the beam's passage through the product (see below), in comparison to the noise, the better the signal-to-noise ratio.

Choosing the right diode size will ensure a better signal-to-noise ratio, and will also enhance the probability of contamination detection. Different diode sizes produce different signal-to-noise ratios, and using too small a diode will result in no or little signal, so the noise will become significant.

By contrast, a larger diode will result in more signal, so the noise will become less significant – resulting in a better signal-to-noise ratio from the x-ray image.

7.6 X-ray Inspection – All About Differences in Attenuation

'Attenuation' is the gradual loss or weakening in intensity of any kind of energy through a medium – so, for example, x-rays are highly 'attenuated' by lead.

The amount of x-ray energy attenuated during an-x-ray beam's passage through a product is affected by the product's thickness, density and atomic mass number. 'Linear attenuation coefficient' is a quality that characterizes how easily a material or medium can be penetrated by a beam of light or energy. A large attenuation coefficient means the beam is quickly attenuated (weakened) as it passes through the medium (Figure 7.1).

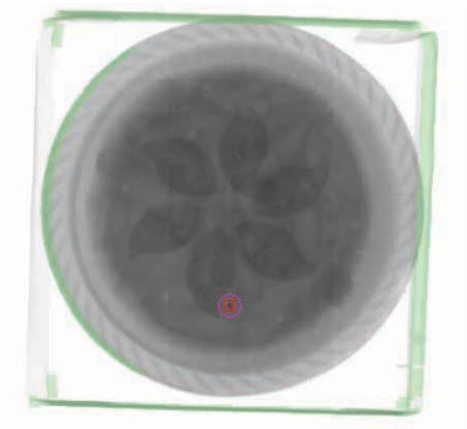

Figure 7.1

When a pack or product passes through the x-ray beam, only the residual energy reaches the detector. Measurement of the differences in attenuation between a product and a contaminant is the basis of contamination detection in x-ray inspection.

7.7 Product Density and Depth

Attenuation of x-rays is proportional to the depth and density of the product through which they travel (see Section 6.1). When a contaminant is present, it attenuates more x-rays than the surrounding product, and appears as a localized increase in attenuation.

The magnitude or 'contrast' of that localized increase is proportional to the contaminant's thickness and the difference in absorption rates between the contaminant and the product. In other words, the same contaminant will show more contrast in a less dense loaf of bread than it would in a denser piece of cheese. Sensitivity within bread is, therefore, better than within cheese.

As the density and thickness of the product increases, more x-ray energy is required to penetrate or pass through it. Increasing the x-ray penetration power (kV) reduces the contrast created by the contaminant – which, in turn, reduces sensitivity (as discussed in Chapter 6). This is because the extra power needed to penetrate the product may tend to over-penetrate the contaminant too.

7.8 Chemical Composition (Atomic Mass Number)

The chemical compositions of both the product and the contaminant also affect overall sensitivity of contamination

detection. Food and pharmaceutical products typically contain compounds made from chemical materials with an atomic mass of 16 (oxygen) and under.

Given that food products are made up of low atomic-mass materials, the x-ray attenuation of the food is proportional to product density and depth. For example, the thicker or denser the product, the more x-rays are attenuated.

A potential contaminant becomes detectable by x-ray inspection if it has a high atomic mass – a feature generally related to the contaminant's density. Food products typically contain low atomic-mass materials, such as water. By contrast, contaminants typically contain high atomic mass materials and generally have a higher density. It's therefore convenient to use density as the benchmark for contaminant detection. Generally, contamination detection is only possible with contaminants that are denser than the product in which they are embedded. (See Section 1.6)

7.9 Texture or Uniformity of the Product

Homogeneous packs are the easiest type of product to inspect, since a constant pack signal means small absorption changes can be readily detected. However, many food and pharmaceutical products are composed of areas of varying absorption caused by more or less product, gaps, or air pockets (see Section 6.1).

7.10 Product Examples

A unit of density is known as 'specific gravity' or SG. Pure water has an SG of 1. Generally, most foods have a density in the region of 1 or slightly less, because they are water-based. As the x-ray system needs to see an increase in density, an object with an identical density remains undetectable, because it simply blends in with the rest of the product.

X-ray systems find contaminants by 'looking' for a change in density within the product. A product will normally consist of a certain overall density in the case of a uniform product, such as a bag of flour or block of cheese, and a combination of peaks and troughs in more randomly-composed materials, such as a bag of potatoes.

The sensitivity of an x-ray system to a given contaminant in a product depends on a number of factors. These include the consistency of the product, its thickness, and the type and size of contaminant to be found. Sensitivity is determined by the size and density of the contaminant, in comparison to the product itself.

An x-ray system will generally find smaller contaminants, and work optimally on a product that's relatively uniform or homogeneous. This is because the system is better able to distinguish any sharp changes or transitions caused by a dense object within the product.

In order to understand how a contaminant is noticeable within a product by virtue of its density, consider the example of a flat beef-burger, which is 10mm thick (Figure 7.2). We can show this pictorially below:

Figure 7.2

Since food has approximately the same density as water, it can be considered to have a density or 'SG thickness' of 1. For a 10mm thick burger, this can be considered as 10 'units', or a total SG (through the object) of 10.

Below are the specific gravities of other typical contaminants:

- Most metals SG = 7 to 8.
- Mineral stone SG = 3.
- Soda glass SG = 3.
- Dense rubbers SG = 2.
- Bone SG = 2.
- Dense plastics, such as PVC, SG = 3.

Now consider the same product with a 1mm metal sphere inside it, as shown below (Figure 7.3).

Figure 7.3

Most metals fall into the SG 7-8 range, and so 7 will be assumed for this example. A contaminant inside the food displaces an equivalent part of that food, so a 1mm contaminant will replace 1mm of product. Taking 9mm of product gives a base product density of 9, to which must be added the density of the metal, which is 1mm at SG = 7.

10mm-high product

9mm of product = SG 9

1mm of metal = SG 7

Total SG = 16

10mm high product

SG total of 10

The total density of the burger at this point is now 16, which is a 60% increase over a normal product, making it very easy to find the contaminant. Generally, non-metallics are around SG = 3, so the effect of a similar-sized non-metallic contaminant in the same product will now be considered.

Using the same equation, 9mm of product has an SG of 9, and 1mm of contamination at SG = 3. The product now has a density (at the point of contamination) of 12, which is a 20% increase over the background product. This is also clearly detectable by the system, but to a reduced contrast ratio (figure 7.4).

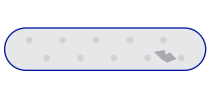

Figure 7.4

Now consider the effect of a thick product on the detection principle: The product considered now might be, for example, a stack of burgers 10 high, giving a thickness of 100mm, which is an SG total of 100.

Using a 2mm metal ball as a contaminant, the product density is now SG = 98. Metal contamination, still at SG = 7, is now 2mm thick, giving a density of SG = 14. Adding these together at the point of contamination gives a density of SG = 112, a 12% change in density.

It can be seen that a thicker product gives a corresponding drop in ultimate sensitivity (Figure 7.5).

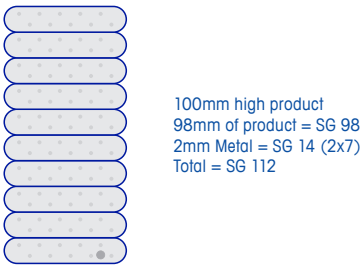

Figure 7.5

In summary, it can be stated that:

- Thinner products give better detection sensitivity.
- A larger contaminant is required in a thicker product in order to maintain the same contrast ratio.
- Smaller contaminants are more easily detected if they are of a dense material.
- To be detectable, lower-density contaminants (such as glass, stone or bone) require a larger particle size.

When looking primarily for metal (which has a high atomic number), a 0.4mm diode is a good choice, providing there's sufficient x-ray dose to penetrate it. This is because, with the presence of metal, there will be radiographic contrast – and there should be enough to deal with a 'noisy' product.

10mm high product

9mm of product = SG 9

1mm of glass/stone = SG 3

Total SG = 12

100mm high product

98mm of product = SG 98

2mm of metal = SG 14 (2x7)

Total SG = 112

However, using a small diode to detect metal will not always lead to large gains in detection sensitivity – it depends on the application. For example, a 0.4mm sphere of metal can quite easily 'hide' in a product with varying density levels; these kinds of products include potatoes, rice or raisins (Figure 7.6) – and so the advantages of using a small diode are negated.

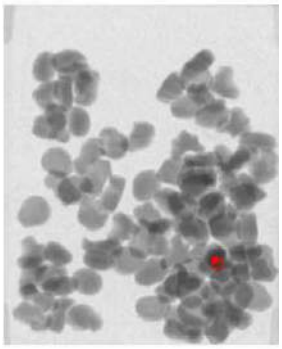

Figure 7.6

Generally, the larger the diode size, the better the radiographic contrast (signal-to-noise ratio) and the better the image quality.

7.11 Product Effect

Product effect refers to random variation (inherent within products), which affects x-ray attenuation and signal-to-noise ratio. Ideally, all products would be homogeneous and produce a consistent radiographic contrast – but, in reality, not all products are homogeneous.

The product effect is the change in density caused by products' natural variations, including their packaging. A bag of rice, for example, will result in a lot of product noise due to the differences in attenuation within the product.

Finding a very small contaminant will, therefore, prove challenging because the contaminant may get 'lost' within the product. This is because the difference between the attenuation levels of the contaminant within the void (a low-density area) is so close to the attenuation level of the material itself that it's not possible to distinguish between them.

By contrast, a block of cheese (Figure 7.7) is homogeneous and dense, which means that the diodes' signals are at a constant level. This results in a better contaminant contrast, because there is less dynamic change in the product.

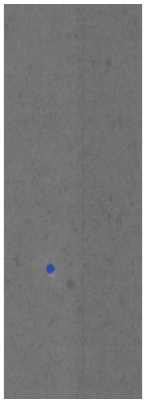

Figure 7.7

If a very small diode is chosen in order to try and achieve the very best level of detection, optimum results may not be possible. This is because there is already a significant amount of voiding, which will hide the density of that contaminant.

Using a very small diode will also result in a low product signal, and the background noise will result in a poor signal-to-noise ratio. So, if a very small diode is chosen to obtain maximum sensitivity, there may be no signal at all, because it's too small to pick up any appreciable level of signal difference between product background and the contaminant.

In addition, there are other interactions, which eliminate the benefits of a fine-pitch diode that can find very small contaminants – all the more so when it's discovered that the contaminants being sought are hiding in voids in the product (e.g. in rice or raisins).

Consequently, there's a balance to be maintained between:

- The size of the diode.
- The amount of x-rays required.
- The cost of the system.
- The kinds of contaminant likely to be found.

For example, by placing a 0.2mm diode in a machine inspecting raisins, results may be no better than from a 1.6mm diode; however, the machine would be far more expensive, since it would require significantly more x-ray dose capability.

7.12 Contaminant Size

Theoretically, it's possible to detect contaminants equal in size to (or larger than) the detector diode. However, with today's advanced image analysis capabilities, this is no longer achievable.

When a contaminant falls between two diodes or scans of the detector, the absorption change created by that contaminant is shared by those pixels which are affected. The smallest size of contaminant detectable is actually most dependent on the product's characteristics, rather than the detector diode size.

Theoretically with a 0.4mm diode, it might be possible to find a 0.6mm contaminant. However this may not, in fact, be achievable, since there might not be enough contrast available within the signal. It could, for example, be affected by product variations or lack of signal-to-noise performance, due to small diode size.

Again, in theory, a 0.4mm diode should be able to find a 2.5mm piece of metal swarf in a 20kg block of cheese. However, this is unlikely because there will be a high signal-to-noise image.

However, with a 1.6mm diode, the resolution will be coarse, though the signal-to-noise will be significantly improved due to the increased diode area. Consequently, contrast of detection will be enhanced, and the probability of finding 2.5mm metal will be greater.

7.13 Which Diode is Best for You?

The optimum diode size depends on the specific application and likely contaminants, as well as the market and the manufacturer's expectations.

Diode size	Advantages	Disadvantages	Applications
0.2mm	Lower spatial resolution.	Cannot be used on larger objects due to the projection effect. Requires a faster scan speed and high x-ray powers.	Ideal for inspecting thin, homogeneous products, e.g. pharmaceutical materials or products in sachets or pouches, such as gravy mixes.
0.4mm	Higher spatial resolution.	Requires more energy, resulting in a greater total cost of ownership. Not suited to inspecting thicker products. Line speed and product depth will limit capability.	Ideal for inspecting slow-moving products that are thin and homogeneous, e.g. sachets and pouches.
0.8mm	This is the standard diode size on most x-ray systems, and is widely regarded as giving the best all-round detection. Generally, it's the best choice in terms of energy consumption, x-ray system cost and performance. It meets or improves on metal detector detection levels.	May not provide best detection on thin, homogeneous products.	Suitable for most applications, including inspecting both thick and thin products.
1.6mm	Provides good radiographic contrast, since larger diode gives more signal, thanks to larger x-ray collection area – and because scan speed can be lower for satisfactory coverage of 1.6mm of belt for every scan.	Lower spatial resolution.	Ideal for inspecting thicker, high-density products, such as cartons; good for finding contaminants between 1.6mm and 2.5mm.

Table 7.1

Notes

X-ray Inspection is More Than Just Contamination Detection

As well as being detectors of physical contaminants, modern x-ray systems can act as multi-tasking protectors of product integrity and brand quality.

In a single pass at high line-speeds, x-ray systems can simultaneously identify contaminants and:

- Measure product mass.
- Count components.
- Check fill level.
- Check head space.
- Identify faulty products.
- Inspect seal quality.
- Spot missing giveaways.

Benefits of x-ray systems include a small footprint, with one machine performing several tasks, instead of several machines – with each one performing a single task. In addition, a single set-up screen ensures quicker and easier line changeovers, which reduces operator errors and minimizes production-line downtime.

Additional inspection features offer a higher return on investment when implemented as part of an x-ray inspection program. These features are discussed in detail in this chapter.

8.1 Length / Width / Area / Volume Measurement

This is the simplest form of pack analysis that's used in conjunction with contamination detection, and is normally termed as 'object finder'. The absorption value (relative to product depth) of each pixel that makes up the 2D gray-scale screen image is known, so a 3D image is actually created for every pack that passes through the machine. This image measures the length, width, volume and surface area (Figure 8.1).

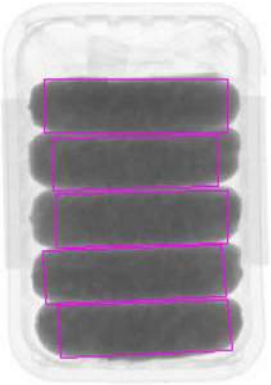

Figure 8.1

8.2 Product Check – Component Count

Since the overall volume and area of the image can be checked, the process can be taken a step further; each individual region of a pack that's been checked (or certain areas showing higher absorption) can be counted.

Figure 8.2 shows two garlic baguettes in a flow-wrapped pack. The manufacturer might have problems with the butter injection machine (it could become blocked or run out of garlic butter), in which case a quality issue could occur because of low volume of garlic butter in each slice that's been cut into the bread. Since the x-ray system can clearly see the amounts of garlic butter delivered to each baguette, these can be individually zoned; the system then checks that the surface area (or volume) in each of these areas meets an acceptable level.

Figure 8.2

For customers in the pharmaceutical industry wishing to comply with FDA requirements and ensure brand protection, an x-ray inspection system can check for many forms of anomalies in blister packs of tablets, at rates of 500 packs per minute.

Figure 8.3 shows how x-ray inspection can detect a missing tablet. This type of inspection can also detect broken tablets and faulty tablet packs, as well as checking for missing product leaflets. According to GMP guidelines, a machine made from hygienic polished-finish 316 stainless steel is fit for purpose for this application.

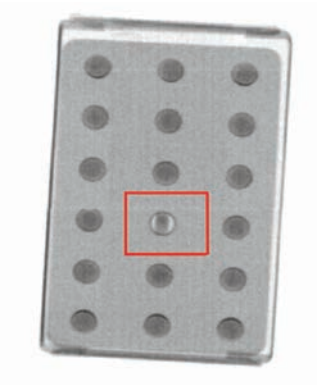

Figure 8.3

8.3 Fill Level

The fill level of products or containers can be checked on both vertical and horizontal x-ray beam systems (Chapter 4 discusses vertical and horizontal x-ray beams in more detail). Consider the example in Figure 8.4, a horizontal-beam machine shows a stack of potato chips in a recycled composite can with a metal base and foil lid. Even through the packaging, the machine can detect stainless steel in the package, as well as concentrated lumps of flavoring, which are composed of hard agglomerates of powder and fat.

Figure 8.4

In Figure 8.5 the stack of chips has collapsed on its side and some chips are broken. By checking the height of the stack, x-ray analysis can detect that the fill level has dropped below an acceptable standard.

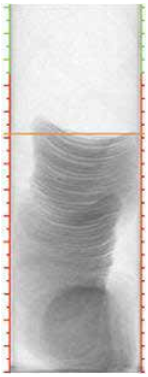

Figure 8.5

A good example of a vertically-inspected zoned fill-level check is shown in Figure 8.6.

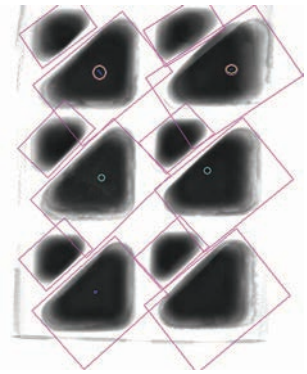

Figure 8.6

An under-fill in one yogurt pot could potentially be compensated for, and followed by, an over-fill in another pot in the same pack. This anomaly could pass undetected on a traditional in-line weighing system, as it can only measure the overall pack weight. Figure 8.7 shows twin-lane inspection of six-pack yogurts; the fill level in one of the pots is low, so the pack is rejected.

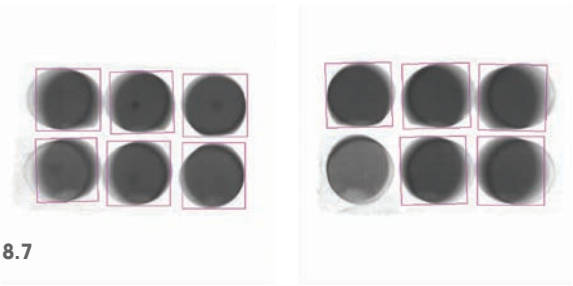

Figure 8.7

8.4 Head Space

Measuring the 'head space' of a product is most commonly applicable where products are packaged in containers in which the distance between the surface of the product and the top of the container/closure is dynamically measured.

Maintaining product freshness is crucial for brand integrity, and measuring head space is important for pasteurization and for the sterility of the product (Figure 8.8).

The head space tool can automatically allow for variations in product fill level and for variations in the height of the container. This capability will ensure that product integrity is always maintained at required levels.

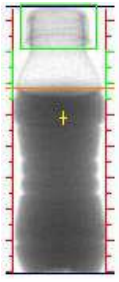

Figure 8.8

8.5 Mass Measurement

An x-ray inspection system creates a 3-D absorption image, in which the gray-scale value (absorption) is the third dimension. The sum of all the gray-scale values in an image is proportional to the mass of that product. By calibrating the total absorption value against a known mass for a particular product, the x-ray system can determine the mass value for each product that passes through the system.

The x-ray system has an auto-learn facility, whereby an acceptable weight pack (close to the nominal weight) is passed through the machine (typically 10 times). The gross weight of the pack is then entered into the system; however, the user must have previously weighed this pack on a set of calibrated static scales that offers a suitable weight range and proper accuracy. When the production line runs, each newly imaged pack has a pro-rata calculation made against the learned reference pack, generating the mass for each new pack.

The relationship between mass and total product x-ray absorption is not a straight line – though using a single-product auto-learn feature is quite accurate when production pack weights are near the target weight. However, more sophisticated systems use a three-product auto-learn process:

1. The low rejection point
2. The target weight
3. The high rejection point

This method allows calculation of the mass from variations in x-ray absorption within a narrower range. It provides greater accuracy than that offered by the normal production weight range.

Accuracy is good on homogeneous packs (e.g. a block of butter) but it's not good on loose-packed products (e.g. sausages in a bag or products where the batch ingredients can vary considerably). X-ray mass measurement can be particularly effective for high-speed applications, where traditional in-line weighing systems may not offer the same level of accuracy.

Packs can be controlled to minimum weight, EU average weight or US zoned weight regulations. Reject reports (and all relevant statistics) can be generated accordingly, and electronic or hard copy documents can be easily produced.

Mass measurement may not be allowed for compliance with weights and measures regulations in every country, since certain countries request R51 type approval, which only applies to gravitational weighing systems.

Figure 8.9 shows a twin compartment ready-meal (TV dinner), for which the overall mass of the pack is being measured. At the same time, the mass of each compartment is being individually checked. In this case, the overall weight is correct, but there is low fill in the rice compartment. The pack is, therefore, rejected.

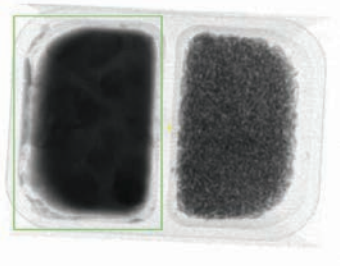

Figure 8.9

8.6 Zoned Mass Measurement

In Figures 8.10 and 8.11, the same principle of product mass measurement is taken to the next level. Here, areas can be zoned; then the mass can be checked separately inside each pack – in this case, for a box of chocolates. In addition to the overall mass of the pack and its content being checked, the mass of each sweet, missing sweets and mispositioned sweets can also be measured.

Figure 8.10

Figure 8.11

8.7 Pack Integrity – Damaged or Missing Packing Components

As well as inspecting the content of a packaged product, an x-ray inspection system can detect dented cans and squashed or deformed packs; it can also check that the closures are in place. Figure 8.12 shows a tube of medical cream which has been rejected because the screw-cap is missing.

Figure 8.12

8.8 Vacuum Sensor

Ensuring a product retains its vacuum is critical to safeguard product freshness and integrity. The vacuum sensor tool inspects products with metal caps on horizontal beam systems and sits just above the product within the x-ray system. The sensor very accurately measures the height in the center of the container's metal cap to confirm the presence of a vacuum.

8.9 Premium Inserts or Presence of De-Oxidizers

Many manufacturers now place giveaways or premium inserts into packs, to entice customers and to promote their sales. These inserts are automatically dispensed into the product and can, sometimes, be missing. In itself, this event could well become a customer complaint. Figure 8.13 shows a small toy in a carton of cereal; each pack is checked to ensure that the toy is present.

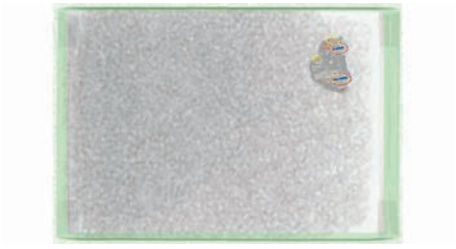

Figure 8.13

In many meat-based products, de-oxidizers (or 'scavengers') are inserted to help keep the product fresh. These can be quite dense and can reduce possible levels of detection. Figures 8.14 and 8.15 show how, in a packet of cooked ham, the x-ray machine can both check that the de-oxidizer is present, and remove it from the x-ray image, for optimum detection in the pack.

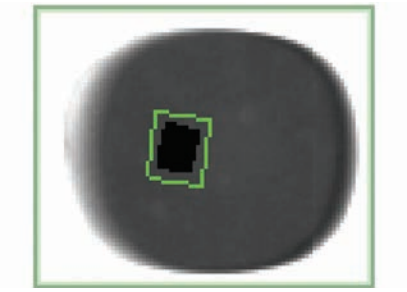

Figure 8.14

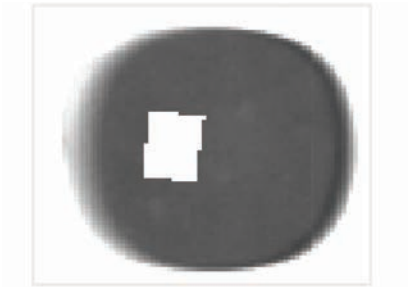

Figure 8.15

8.10 Product-in-Seal Inspection

For manufacturers of sealed food and pharmaceutical packs, it's very important that the seal is fully intact. If the seal is compromised, the product may have deteriorated by the time it reaches the supermarket shelf, or it may no longer be sterile.

A special ultra-high contrast detector system can be used to check the seal area on low-density packaging. This can be carried out simultaneously with contamination and product integrity inspection. Figure 8.16 (a pack of biscuits) shows the image created and how the system checks for the presence of dense material between the outer and inner edges of the seal. If it detects material in this area, it knows that the seal will be weakened or possibly broken and will therefore reject the product.

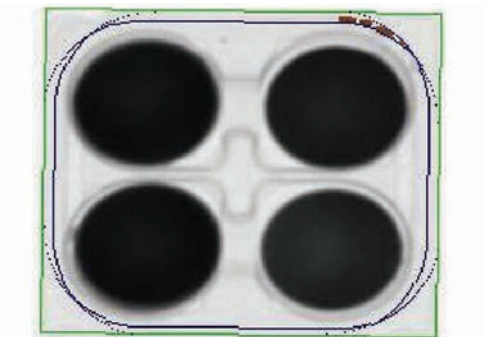

Figure 8.16

An example relevant to the medical industry is the inspection of surgical wound dressings (Figure 8.17). The x-ray checks that the wound dressings are not trapped in the seal and that the pack is kept sterile.

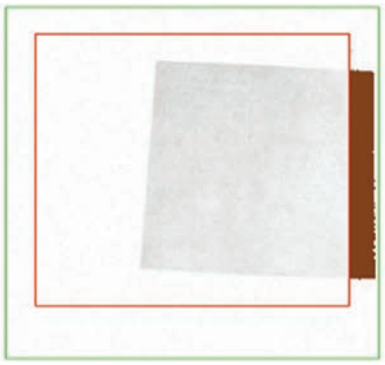

Figure 8.17

8.11 Non-Food and Pharmaceutical Applications

Many x-ray systems (originally developed for food and pharmaceutical applications) are now used in a number of other manufacturing environments and applications. Figure 8.18 shows how the x-ray system checks and confirms the presence of buttons/poppers and zips on a leather coat. At the same time, it checks for any dangerous broken needles that may have been left over from the stitching process.

Figure 8.18

X-ray Inspection is More Than Just Contamination Detection

Figure 8.19 shows an asthmatic inhaler being x-rayed to verify the correct and accurate placement of all the required components.

Figure 8.19

Choosing a Complete X-ray Solution

When buying capital equipment, forward planning (plus the right knowledge and advice) can help instill confidence that the item to be purchased is a good investment.

Purchasing an x-ray system represents a significant capital investment – and the implications of such costs can make it a daunting prospect for food and pharmaceutical manufacturers. What's more, with so many options available, it's easy to feel overwhelmed with the choice of models available, different prices – and the wealth of trial results available for study.

With many suppliers now offering x-ray inspection solutions, it's relatively easy to find an x-ray provider, ask for a quote – and then simply buy an x-ray system based solely on cost. Alternatively, after a product trial, manufacturers may be influenced by an x-ray system that appears to offer the most sensitive product inspection. However, making an impulse purchase based on these factors alone, can have huge repercussions, if the wrong decision is made.

Whether purchasing an x-ray system for the first time or replacing an existing system, this chapter is designed to make the purchasing process easier. It comprises:

- 11 key steps that should be followed when considering investment in an x-ray system.
- Appropriate questions to ask x-ray suppliers, so as to choose a comprehensive x-ray solution that's the right choice – and which offers maximum value for money.

9.1 Value Package

A 'value package' refers to everything consumers consider and evaluate when deciding whether to buy something – in other words, a product is far more than just a tangible item on a shelf. It consists of:

- The tangible services offered with the product, such as a warranty, advice, delivery and maintenance/repair.
- Intangibles such as quality, prestige and reputation.

When purchasing an x-ray system, the term 'value package' means trying to get the best x-ray system with the best functionality at the best value. This means value for the

manufacturer's business, value for their customers, plus commercial value.

Defining value in relation to an x-ray system may also raise questions such as:

- Is it efficient?
- Does it use low power which will save money in the long term?
- Is it reliable or will it require a belt replacement every six weeks?

It's important to keep in mind that there must be a balance between the price a manufacturer pays for an x-ray system and what they receive in return for their investment. For example, if a manufacturer conducts a Hazard Analysis and evaluates their risk is glass in a glass container, it's unlikely they will buy a very small single-beam machine because it's cheaper.

In this example, a value package is about ensuring a manufacturer selects an x-ray system that can give them the best detection of glass (in addition to other functionalities), in order to give them the best overall value for their money.

9.2 Key Steps

Below are 11 key steps a manufacturer should follow when considering whether to purchase an x-ray system:

1) Conduct a Hazard Analysis
2) Identify Critical Control Points (CCPs)
3) Define commercial and operational needs
4) Understand the key drivers for implementation of an x-ray inspection solution
5) Conduct market research to compile a shortlist of possible x-ray suppliers
6) Ask an x-ray supplier what support is available during the project stage
7) Establish critical limits for each CCP/test product
8) Assess the x-ray system's key functions
9) Decide whether an on-site trial or performance purchase agreement is required
10) Consider final factors
11) Make an investment decision

9.3 Hazard Analysis and Critical Control Points (HACCP)

Hazard Analysis should be the starting point for an effective x-ray inspection program (HACCP is discussed in more detail in the Introduction section of this guide). The following sections discuss the 11 key steps in more detail.

Step 1 – Conduct a Hazard Analysis

When considering investment in x-ray inspection equipment, manufacturers should conduct a Hazard Analysis for every product they produce, assessing the risk of contaminants being present. This process should be undertaken before contacting an x-ray supplier.

A 'safety hazard' can be defined as anything that could be a threat to human health. Since x-ray inspection only catches physical contaminants, the term 'safety hazard' here means physical threats to human health, such as fragments of mineral stone, glass, metal, calcified bone or high-density plastic and rubber, all of which could potentially find their way into food and pharmaceutical products.

A Hazard Analysis requires that all hazards which may be reasonably expected to occur (including hazards associated with processes and facilities) are identified and assessed. The potential sources of contamination also need to be identified. It is important to bear in mind that different types of contaminants can cause potential contamination at different stages of the process.

If a specific type of contaminant is common, this should be highlighted from the beginning , because it will have a bearing on the most suitable type of x-ray system for the application.

Step 2 – Identify Critical Control Points (CCPs)

The second stage of HACCP – identification of Critical Control Points (CCPs) – helps in the choice of optimum location/s in which to install an x-ray system. A CCP is a step or process essential to ensuring the highest levels of product safety; it's the point at which control must be applied to reduce the risk of contamination to acceptable levels. See Chapter 13 for a full explanation of CCPs.

Step 3 – Define Commercial and Operational Needs

It's important for manufacturers to clearly define their specific commercial and operational needs before contacting an x-ray supplier. While commercial needs are concerned with obtaining the best value for money, operational needs refer to factors such as ease of use. For example: how easy is it to make line and product changeovers?

It's vital that product manufacturers assess their requirements and compile a wish list before establishing what is available on the market. Having a defined list of the features they want (as well as knowing what they can afford) will make the acquisition process easier by having a clear set of purchasing criteria.

Step 4 – Understand the Key Drivers for Implementation of an X-ray Inspection Solution

Understanding key drivers (factors that influence or 'drive' the outcome of an activity) is also fundamental to choosing a complete x-ray solution. For example, some independent manufacturers may simply wish to purchase one machine; other purchasers will be part of a large national or international company, with clear rules about the purchasing of x-ray machines. These can include factors such as budget, machine quality, machine features, and the availability of local after-sales support services. A reputable x-ray supplier will be happy to discuss a manufacturer's key drivers to ensure they fully understand their requirements, before striving to meet them.

Step 5 – Conduct Market Research to Compile a Shortlist of Possible X-ray Suppliers

Before approaching an x-ray supplier, it's advisable to gather information about them and research whether they can provide precisely the x-ray system required. It's particularly important to find out whether certain suppliers can offer application expertise.

A key question to ask is whether an x-ray supplier has similar machines running in other factories on similar applications.

Some x-ray suppliers have a catalogue of standard products, and they offer a standard x-ray solution (often based on pack size and belt speed), irrespective of a manufacturer's individual needs. However, failing to take into consideration individual requirements (such as the type of packaging used) can lead to problems with product transfer on and off the conveyor. This approach also means that it will be impossible to make an x-ray system longer or shorter to fit a manufacturer's production line.

By contrast, market-leading x-ray suppliers can offer customized solutions; for example, x-ray systems can be built to fit available space, negating the need to alter production lines to fit in an x-ray system.

These factors make it important to ascertain whether a standard model is suitable or whether a customized solution is required – and manufacturers should speak to other food and pharmaceutical manufacturers about x-ray suppliers they have dealt with, in order to gain feedback about those manufacturers' experiences.

Step 6 – Ask an X-ray Supplier What Kind of Support is Available During the Project Stage

To ensure that an x-ray system will be fit for purpose, a reputable x-ray supplier will be able to offer support during the project stage of x-ray machine acquisition and installation. For example, they should be able to supply technical documentation to support the installation, covering matters such as power, air supply and 'layout drawings'.

'Layout drawings' are dimensional drawings of the proposed x-ray system, which indicate its length, width and height, including the height from the floor to the conveyor, the height of the reject bin, the location of the reject device and the height of the Human-Machine Interface (HMI). The purpose of layout drawings is to enable manufacturers to determine whether a particular x-ray system will fit their line.

Step 7 – Establish Critical Limits for each CCP/Test Product

From their HACCP analysis, manufacturers should have determined the types and typical sizes of contaminants they wish to detect. Product testing is then crucial to determine whether their aims are achievable.

'Critical limits' are specified safety limits at manufacturers' CCPs. These limits separate acceptable product (safe food or drugs) from unacceptable product (unsafe food or drugs). Operating sensitivities imposed by external organizations, such as retailer and consumer brand codes, should always be considered as the minimum acceptable standard.

The detectability of contaminants in products using x-ray inspection depends on various factors such as product density and product thickness.

It's important to evaluate whether an x-ray system offers the best contamination detection on the market, while generating minimum false rejects (incorrectly rejected 'good' products). However, there needs to be a balance between high detection and low false rejects, which means setting realistic critical limits for each CCP, and acknowledging that laboratory conditions can't compare to real life.

Product testing is essential because it initiates discussions between a manufacturer and an x-ray supplier, and confirms whether x-ray inspection is suitable for a manufacturer's specific application. For example, if a manufacturer's complaints are based on the presence of hair, wood and insects in product, x-ray would be impractical because it can't detect these contaminants. However, if detecting 0.8mm stainless steel and 2.5mm glass are a manufacturer's biggest concerns (and part of their HACCP risk analysis), product testing will provide reassurance that x-ray offers a viable solution.

A reputable x-ray supplier will be happy to conduct initial product testing on the suggested x-ray system/s. The x-ray supplier should be able to provide detailed product test reports and follow-up discussions, which will enable a joint decision to be made on the optimum solution.

It's important that manufacturers know how they would like to test their product/s and what they would like to gain from the product testing, in order to feel confident that they have obtained a reliable set of data.

The recommended testing protocol – 'Setting the Critical Limits' can be founded in Appendix 1 at the end of this chapter.

Step 8 – Assess X-ray System's Key Functions

It's important to check that an x-ray system meets key functionality requirements. For example:

Is it easy to use?
Can operators be trained quickly to use the x-ray system?
Does it enable quick product changeovers?
Does it allow easy storage and retrieval of date-and-time-stamped images and data, for full traceability?

Advanced x-ray systems are capable of storing images of all rejected packs. These images are date-and-time stamped with the product name, and can be taken off the x-ray machine, then stored on a manufacturer's computer in chronological order.

In this format, they offer excellent traceability for any customer complaints or returns, since the production times/codes can immediately be cross-referenced.

Another key consideration is whether the x-ray system will be robust and reliable, so as to suit the environment in which it will function.

A variety of materials is used in the construction of x-ray equipment, and it's important that they are completely compatible with the product and the environment, as well as with cleaning and sanitizing chemicals. A reputable x-ray supplier will ensure that equipment is corrosion-resistant, non-toxic and mechanically stable. They will also ensure that it can be easily cleaned and maintained to ensure that it performs as expected – and that it will not cause microbiological problems.

Stainless steel is the preferred general-use metal for surfaces which come into contact with food. This is due to its corrosion resistance and durability in most food applications.

When choosing an x-ray solution, it's important to ensure that it's fit for the intended purpose. Equipment should be designed and constructed with due consideration to the industry and environment, as well as to the application in which it will operate.

Each industry has its own special set of sanitation requirements; for example, if the product is a high-risk food product, such as meat or dairy, equipment should be constructed to withstand deep cleaning and sterilization, in order to avoid expensive repairs resulting from water ingress.

X-ray solutions are available with IP65 sealing as standard – and this will deal satisfactorily with most sanitary requirements.

IP69 sealing is available for equipment used in harsh wash-down environments, typically in meat, fish and poultry applications, where there is a higher risk of water ingress (Chapter 5 covers the 'Key Design Features' of x-ray inspection systems in more detail).

Step 9 – Decide Whether an On-site Trial or Performance Purchase Agreement is Required

When a manufacturer agrees to buy an x-ray system, if necessary, an x-ray supplier should offer an on-site trial or performance purchase agreement – providing the system meets certain pre-determined performance standards. This allows manufacturers to evaluate the recommended x-ray system on site and make a final decision as to whether it provides the best solution.

To achieve a successful trial, it's essential that manufacturers have clear objectives regarding what they expect the trial to achieve before it begins. It's also important to remain realistic about detection levels, particularly as the x-ray system will be performing in a real-life production environment, rather than under test conditions in a laboratory. Allowances should also be made for natural product and production-line variations.

A detailed checklist of points to consider when preparing and conducting an on-site trial can be found in Appendix 2 at the end of this chapter.

Step 10 – Consider Final Factors

To ensure that manufacturers secure the correct value package, consideration should also be given to an x-ray system's Overall Equipment Effectiveness (OEE) and Total Cost of Ownership (TCO).

OEE quantifies how well a manufacturing unit performs relative to its designed capacity, during the periods when it's scheduled to run. OEE measurement is also commonly used as a Key Performance Indicator (KPI) in conjunction with lean manufacturing efforts, to provide an indicator of success. OEE is defined by two metrics that indicate the gap between actual and ideal performance:

- OEE quantifies how well a manufacturing unit performs relative to its designed capacity, during the periods when it's scheduled to run.
- Total Effective Equipment Performance (TEEP) measures OEE against calendar hours.

TCO is discussed further in Chapter 18.

An overview of the costs (and possible savings) of a typical installation can be found in Appendix 3.

Market-leading x-ray systems are available which are network-compatible (see Chapter 21 for connectivity options available), allowing remote access by technicians to quickly diagnose and correct issues.

Other topics for discussion include finding out whether spare parts are held in the country, and what sort of programs are in place for preventative maintenance and training.

To ensure that product inspection systems operate at optimum performance with the maximum possible uptime, they must be correctly maintained throughout their service life. A planned preventive maintenance program should be in place – and this should aim to limit wear and tear on equipment that might otherwise result in contamination or contribute to a reduction in performance.

This ensures that problems with this sort of program can be addressed before a breakdown occurs. The verification process should typically take place every 6 to 12 months and, ideally, should be carried out by a trained engineer in accordance with an agreed service contract.

Market-leading x-ray system suppliers offer performance verification testing to keep systems in peak condition.

Before making a final decision, it's also advisable to find out whether any technical symposiums are scheduled and what documentation is available (i.e. manuals, certificates, schematics, IPac).

Step 11 – Make an Investment Decision

Manufacturers who have followed these steps should now find they have the knowledge and information to make an informed purchase decision.

Appendix 1

Recommended Testing Protocol – Setting the Critical Limits

- Manufacturers should establish their 'expected' and 'ideal' critical detection limits on different contaminants, and discuss these with the x-ray supplier. These should be based on manufacturers' risk analysis of the production processes involved, as well as supplier codes of practice, specific current contamination issues and previous customer complaints.
- The x-ray system should, initially, be set up by the x-ray supplier and then optimized before actual testing is made, with consideration for the presence of all contaminants.

Setup

- Manufacturers should be prepared to provide the x-ray supplier with a minimum of 10 clean packs of each different product to be tested.
- The x-ray system should be set at the same belt speed as the 'real' production line.
- It's best to focus on one product at a time.
- The x-ray supplier will pass the 10 different clean packs through the machine to 'learn' the product, i.e. the machine measures and records the characteristics that define a clean pack. Then, as it scans other packs, it can compare their scan data with the clean pack data. Where there is an appropriate anomaly in the two data sets, the machine can reject the pack that differs sufficiently from the clean pack.
- The 'learn' process on modern x-ray systems is usually extremely accurate, but the system can also be manually tuned for improved detection – this is called 'optimization'.
- Optimization involves setting the limits more precisely or so that they are better suited to a particular contaminant. There should then be a short pass of adapted packs, each of which contains these contaminants, to verify what can and can't be reliably detected.
- As well as using calibrated test pieces (of the expected size of detection) to determine if the set-up is in the right 'zone', it's important that manufacturers' specific foreign bodies are also used, with a small sample test run.
- Once detection optimization is complete, the x-ray supplier should pass 25 different 'clean' packs of the same product through to ensure zero false rejects are recorded.
- Testing can then commence, ideally with no further adjustment to the settings.

Testing Guidelines

- Testing should commence using calibrated test spheres. Tests should be made on stainless steel and glass test spheres, before being made on manufacturers' specific contaminants.
- Contaminants can either be placed on the pack or embedded in the pack (the latter is most representative of a real scenario).
- When in a competitor comparison test situation – the same test spheres should be used to test all competitors' machines – especially glass test spheres. Glass spheres from the same category e.g. Soda Lime Glass, can exhibit very different absorption levels. Even if the size and density are similar, the chemical composition can have a large impact on the size of sphere detectable. This should be discussed with the x-ray supplier, and all factors considered for the glass test spheres selected for testing.
- If glass packaging is used, it's recommended that the glass test pieces are made of the container glass, since this glass type is most representative of a possible foreign body.
- If glass is deemed a high-risk foreign body (in addition to calibrated glass test spheres), it's recommended that manufacturers try some irregular-shaped glass fragments, since these will provide the greatest challenge to optimized 'software algorithms' (a set of instructions to perform a specific task – in this case, detection of contaminants). In 'real' production, a glass foreign body is unlikely to be a perfect sphere – it will be a shard. On testing, the dimension of glass fragment directly in the path of the beam (depending on the orientation of the fragment), should be the size recorded as the detectable limit.

Test Procedure

- The manufacturer should pass each contaminant-containing pack 25 times through the machine, and record the number of detect/non-detect. Multiply x 4 = % Probability of Detection (POD).
- The manufacturer should repeat the above step by passing 25 non-contaminated packs through the machine, and record the number of detect/non-detect. Multiply x 4 = % Probability of Detection (POD).
- If any false rejects (incorrectly rejected 'good' products) occur during the 25 passes, the number of 'detect' results may still be recorded, if it's thought that these false rejects can be easily tuned out. However, if it's decided that the false reject occurred too easily or at too high a rate, then the machine is set too acutely and the test should be stopped. The product should be re-optimized and the 25-pack pass (for zero false rejects) made again and accepted, before the test is re-started.
- It's important that manufacturers remain realistic about detection levels. Allowances should also be made for natural product and production-line variations.

- If the product is not homogeneous, or if the packaging itself presents inspection challenges, then the controlled test sample pack passes should be carried out in different areas of the pack, and the results be recorded individually. An overall POD by volume of the pack can then be easily calculated.

Appendix 2

How to Undertake a Trial – Checklist

Prerequisites

Before embarking on a trial, it's important that manufacturers can answer the following questions:

- What do they want to evaluate or see from the x-ray system being on site?
- What is their definition of a successful trial?
- Will the trial be in-line or off-line? What are the reasons for this? (Off-line is usually easier).
- If the trial will be off-line, what product will be made available and when? Is there space to store product in pallets?
- What manpower will be available to feed and remove product from the machine?
- If the trial will be in-line, have they agreed with the x-ray supplier on the proposed machine specification and its integration? Factors to consider include: physical space available; throughput; environmental conditions; air and power requirements; guide rails, line speeds, conveyor transfers, and modifications to the factory construction e.g. moving a wall or mezzanine floor or fixing the x-ray system in place. Will the x-ray system act as a CCP while it's on trial and therefore will the reject device need to be enabled? Does the x-ray system need to be retailer-specification compliant?
- How will the x-ray system be operated during the trial? Factors to consider include: who will be trained on how to use it? (i.e. setting up new menus, adjusting parameters) Who will evaluate its performance? (i.e. ease of use, ease of maintenance, reliability and build quality).
- What are the detection performance test criteria?
- What test samples will be used?
- Will they follow the x-ray supplier's guidelines on performance verification or do they have their own?
- What would be the acceptable false reject rate?
- If the x-ray machine is simultaneously measuring mass, identifying missing products or monitoring fill levels, who's making up the defect packs? Are they representative for the trial?
- How long would they like the x-ray system on site? (One week is usually enough since, after two to three days, manufacturers will get a clear indication of exactly what's possible with the x-ray system).
- Who will be the primary host on site? (In addition to the machine operator or evaluation champion).
- When will they compile the results? How long afterwards will they make a decision?

Appendix 3

Calculating the Total Cost of Ownership (TCO) for an x-ray Inspection System

Overview of the costs of a typical installation. Manufacturers should enter their values below:

Costs of initial investment	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Purchase price						
Installation/commissioning (initial operation)						
Validation documents						
Official verification costs (if applicable)						
Training with the supplier or on site with the system						
Procurement costs for spare parts packages						
Service contract						
Integration into the production line						
Disposal of old equipment						
Other						
Total						

Subsequent years (generally up to 5 years)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Operating costs						
Maintenance costs						
Unplanned downtimes						
Guarantee/warranty extension						
Official verification costs (if applicable)						
Software/hardware updates and support						
Personnel costs						
Service contract						
Mandatory schedule user performance testing costs						
Other						
Total						

Although the costs associated with purchasing an x-ray system are a key focus for manufacturers (especially for management and decision makers), consideration of the potential savings, in particular over the entire lifetime of an x-ray system, can be decisive when making an investment decision. It's worthwhile therefore including the varying savings potentials and allowing them to influence the TCO calculation.

Choosing a Complete X-ray Solution

Overview of the possible savings of a typical installation:

Savings	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Reduction of waste						
Reduction of rework						
Reduction of work required						
Reduction of product 'giveaway'						
Avoidance of returns						
Protection of brand reputation and customer relationship						
Reduction of expense involved in audits						
Reduction in lost downtime						
Reduction in the costs of mandatory testing						
Other						
Total						

For further, in-depth information on the costs and savings mentioned in this appendix, please refer to Safeline x-ray's Calculating the Total Cost of Ownership for x-ray Inspection Equipment white paper.

Notes

Reasons for an X-ray Inspection Program

This chapter examines the case for investing in x-ray inspection technology – the primary reason for which is to provide a wide-reaching contaminant reduction program. Such a program firstly seeks to prevent sources of contamination, and then implements effective preventive actions if contamination is detected within a product.

10 Reasons for an X-ray Inspection Program

There are many other reasons for acquiring and installing a well-designed x-ray inspection program. These reasons can be summarized as follows:

- X-rayed product is premium.
- Minimizing foreign body contamination.
- Minimizing costs.
- Protection of the customer and consumer.
- Protection of brand and reputation.
- Certification.
- Employee buy-in.
- Risk management and regulatory compliance.
- Retailer and consumer brand codes.
- Pack integrity analysis.

10.1 X-rayed Product is Premium

More and more food manufacturers and packagers are keen to tell their customers that they are using x-ray inspection systems. The process is seen as adding a higher level of quality and production to a premium product – and use of x-ray inspection may well help companies to win new business from competitor suppliers who don't have product inspection systems in place.

10.2 Minimizing Foreign Body Contamination

X-ray inspection systems are designed to identify and remove dense contaminants from product. Nevertheless, contaminants can still cause consumer complaints, although these are not normally due to the x-ray system failing; they are usually associated with a lack of effective controls, poor working methods, incorrect system specification and design – or a combination of these factors. Furthermore, such complaints don't necessarily relate simply to the presence of tiny pieces of metal, glass or mineral stone, but often to larger items such as washers, bolts and pieces of blades that should be detectable by even the most basic type of x-ray system.

A well-designed x-ray inspection program can deal with these issues by focusing on how to minimize instances of contamination in the first place, through:

- Good Manufacturing Practice (GMP).
- Prerequisite programs.
- Selection of the correct equipment.
- Location of inspection equipment.
- Effective testing.
- Gaining a greater understanding of how industry standards, customer requirements and legislation affect manufacturers.

Further information is available in Chapter 12.

10.3 Minimizing Costs

The costs associated with implementing and maintaining an effective x-ray inspection program are significantly lower than the potential costs of failure.

Of course, a contaminated product found before it's shipped to its customer destination will, inevitably, result in product and packaging waste, as well as possible machinery damage and loss of output; and costs can be high when resulting in output loss – particularly on high-volume automated production lines.

However, such costs can be put into context by instances of contamination discovered after shipment. These can result in loss of customer satisfaction, product recall, adverse publicity and potential legal action – all adding up to significantly higher long-term costs and long-term damage.

Time and money spent minimizing internal waste, decreasing loss of output and reducing complaints will inevitably yield a better return than money spent on resolving problems after they have occurred. So a properly-implemented x-ray inspection program will lead to reduced failure costs and improved customer satisfaction, enhanced profitability and better protection of the manufacturer's brand.

10.4 Protection of the Customer and Consumer

Although modern manufacturing techniques constantly strive to eliminate the occurrence of contaminants in products, there will always be occasions when processes or procedures break down, resulting in contamination.

Manufacturers and their employees have an obligation to customers and end consumers to minimize the occurrence of contamination, to ensure consistent quality is maintained and to take all possible steps to protect the customer and end consumer. Failure to achieve this can create potential animosity between the retailer (and/or customer) and the manufacturer – resulting in breakdown of the customer relationship and loss of future business opportunities.

10.5 Protection of Brand and Reputation

Powerful product branding gives customers a perceived assurance of safety and quality. Branding is also responsible for generating repeat purchases, so it's an important contributor to maximizing sales and justifying premium product prices charged by manufacturers and retailers.

For this reason, an organization's responsibility is not only to the end consumer, but also to the brand and to the reputation of the manufacturer. Brands are assets to be managed carefully and should be protected from any form of adverse publicity. Contaminated product in the hands of consumers can have a serious negative impact on any organization, with consequent damage to the brand, as well as potentially costly recalls.

In the event of a company being investigated as a result of a customer complaint, properly-completed documentation will provide invaluable evidence of the correct operation of the x-ray inspection program.

10.6 Certification

The importance of x-ray inspection systems in ensuring product safety makes it highly likely that x-ray systems will be the focal point of customer or retailer audits. Evidence of an effective program will be requested at some time, in support of any one of a number of audit processes, such as:

- Internal food safety and management system audits
- Customer audits
- Quality management system audits
- Food safety management system audits such as SQF

10.7 Employee Buy-In

When formalized procedures and working practices are implemented in order to protect product integrity, these processes will demonstrate to employees the importance of protecting product, brand and the reputation of the company.

All these factors can affect jobs and job security, so employee commitment to these procedures is crucial to their own security, as well as to the success of the company.

10.8 Risk Management and Regulatory Compliance

Currently, there's no broad-based legal requirement forcing manufacturers to install x-ray inspection equipment or implement x-ray inspection programs. However, in any legal proceedings which result from contamination in a food or pharmaceutical product, manufacturers could be called upon to prove they have implemented procedures to manage and prevent all identified risks in their processes.

Failure to do so could result in serious consequences; however, it's easier to provide an adequate defense when an organization has a documented system which continually assesses the risks to food safety and allocates resources to minimizing these risks.

An x-ray inspection system provides superior levels of detection, particularly in glass jars, glass bottles, metal cans and most common products in foil or metalized film packaging. Consequently, the use of an x-ray inspection system can be regarded as proof of implementing the highest level of inspection available, as well as evidence of adhering to a comprehensive HACCP program.

In the absence of any definitive legislation covering x-ray inspection requirements, several regulatory bodies have emerged with standards and codes of practice for manufacturers; they advocate universal inspection of all food and allied products by x-ray inspection equipment.

Some of these standards are beginning to play a part in supplier selection and the specification of x-ray inspection standards for manufacturers. To demonstrate that they are adhered to, these standards must usually be achieved in accordance with a well-documented and formal program.

10.9 Retailer and Consumer Brand Codes

Major retailers and owners of leading consumer brands have also developed their own codes of practice, which need to be adhered to in order to satisfy supply agreements (section 3.4.5 lists some of the most widely used examples). These standards can vary considerably across geographical territories – though increasingly, the implementation of a formal x-ray inspection program is expected before supplier approval is granted. (See section 4.7)

10.10 Pack Integrity Analysis

Normally, a contamination elimination/reduction system will not earn a food or pharmaceutical manufacturer/packager revenue or return on investment at the same level as a filling machine or a checkweigher.

However, x-ray inspection is much more than simply a contamination detection system; it can help to increase Overall Equipment Effectiveness (OEE), as can be seen in Chapter 9.

X–ray inspection can also provide many additional (and simultaneous) pack integrity inspection checks on the same machine (see Chapter 8), which can be economically beneficial.

10.11 References

Links to various sources and types of information are included below for reference:

British Retail Consortium (BRC)

http://www.brcglobalstandards.com

British Standards – PAS 96

http://www.bsigroup.com

CIES – International Committee of Food Retail Chains

http://www.theconsumergoodsforum.com/

Codex Alimentarius

http://www.codexalimentarius.org

European Food Safety Authority (EFSA)

http://www.efsa.europa.eu/

Food and Agriculture Organization (FAO) of the United Nations

http://www.fao.org/

Food Standards Agency (FSA)

http://www.food.gov.uk/

International Featured Standard (IFS)

http://www.ifs-certification.com

Safe Quality Food (SQF) Institute

http://www.SQFI.com

United States Department of Agriculture (USDA)

http://www.usda.gov/wps/portal/usdahome

United States Food and Drug Administration (FDA)

http://www.fda.gov

World Health Organization (WHO)

http://www.who.int/en/

World Food Safety Organization

http://www.worldfoodsafety.org/

Notes

Building an Effective X-ray Inspection Program

A quality control and contamination detection system is only as good as the in-house procedures that support it. This chapter looks at the factors that support a successful and effective x-ray inspection program.

11.1 Program Requirements

The adoption of an x-ray inspection program should be a strategic decision for the organization, otherwise there's a danger that the program will lose its importance and will not be effectively maintained. The design and implementation of the program should be governed by:

- The various needs and objectives of the organization.
- The product range manufactured.
- The processes employed.
- The size and structure of the organization.

The program needs to be proactive rather than reactive; it should be used to prevent the occurrence of contamination, rather than just detecting it and then eliminating product and/or packaging defects. The aim should be to have complete control over the entire production process, from the quality of supplied ingredients, through to dealing with customer and end consumer complaints.

11.2 Key Elements and Controls

Those responsible for defining and documenting the x-ray inspection program should have a good understanding of basic operating principles and equipment capabilities in order that their expectations should be fulfilled once the equipment is operational (see Chapters 1 to 10). If the correct x-ray inspection solution is not identified in the first instance, then subsequent implementation of the x-ray inspection program may be of little benefit.

Once the basic principles of operation have been understood, and once the best x-ray inspection solution has been selected, it's important to understand the key elements that need to be implemented in order to make the program effective.

Key Element	Chapter
Prevention of Foreign Body Contamination	12
Selecting Critical Control Points	13
Operating Sensitivity	14
Installation, Commissioning and Training	15
Performance Verification and Auditing	16
Dealing with Suspect and Rejected Product	17
Total Cost of Ownership (TCO)	18
Due Diligence	19
Data Analysis and Program Improvement	20
Connectivity Solutions	21

Table 11.1

The specific controls contained within the program should be based on an analysis of hazards and frequency of their occurrence, together with the nature and size of the business. Table 11.1 highlights the key elements, and references the sections of this guide that review the requirements in more detail.

11.3 Documenting the Program

The x-ray inspection program should be documented as a set of controlled policies and procedures. The scope and detail of the procedures should reflect the size of the organization, its complexity – and its lines of communication.

For a small organization, it may be possible to establish the necessary controls within one single operational procedure; in a larger organization, it may be better to integrate such requirements into the existing safety or quality management system.

The most effective x-ray inspection programs are established, documented, operated and maintained within the framework of a structured safety management system. This, in turn, should be supported by the organization's overall management activities.

Relevant and meaningful documentation is very important, and in the event that a company is investigated because of a customer complaint, documentation will provide necessary evidence of production process history. Furthermore, documentation can also form the basis of a robust due diligence (see Chapter 19) defense by demonstrating that, throughout the manufacturing process, a manufacturer took all reasonable precautions to avoid the breach of food safety regulations. Such steps can include setting up systems of control which are appropriate to the risk, as well as having procedures in place which review and audit the x-ray system to ensure it's operating effectively.

11.3.1 Image Library

Market-leading x-ray systems store images of all rejected packs. These images are date-stamped and time-stamped with the product name. These details can be taken off the x-ray machine and stored on a manufacturer's computer in chronological order. In this format, they offer excellent traceability in the event of a customer complaint/return, since the production times/codes can be immediately cross-referenced.

Features such as USB and Ethernet ports allow immediate access to statistical data and reject images, which can assist manufacturers with quality reporting, traceability and HACCP compliance. Such information can also prove critical in helping manufacturers demonstrate due diligence; this is because the supporting evidence must include data confirming the number of packs inspected, as well as the number of packs rejected as a result of potential contamination events.

11.3.2 X-ray Inspection Policy

Senior management should define and document the company's x-ray inspection policy. When defining the policy, consideration should be given to ensuring that it:

- Is appropriate to the role of the organization with regard to its position in the food chain or pharmaceutical manufacturing process.
- Supports any applicable regulatory, retailer, customer or corporate safety and quality requirements.
- Is communicated, implemented and maintained at all levels within the organization.
- Is reviewed for continued suitability.
- Is supported by measurable objectives.
- Defines individual responsibilities in the event of product rejection and x-ray inspection system faults.

11.3.3 Responsibilities and Authority

Management should ensure that responsibilities and authorities are clearly defined and communicated to all relevant personnel within the organization. This will ensure the effective operation and maintenance of its x-ray inspection program.

All company personnel should be individually responsible for reporting potentially-hazardous situations and problems associated with the effective operation of the x-ray inspection program; they should also know who to report to.

11.3.4 Documented Procedures

For the program to be effective, procedures should be:

- Appropriate to the organizational needs of the facility with respect to food and pharmaceutical safety.
- Appropriate to the size and type of the operation, and the nature of the products being manufactured or handled.
- Implemented across the entire production system, either as generally applicable programs or as programs applicable to a particular product or operational line.
- Approved by those responsible for food and pharmaceutical safety.

11.3.5 Records / Traceability

Records should be established and maintained to provide evidence of conformity to requirements; these records should also demonstrate the effective operation of the x-ray inspection program.

Records should remain legible, readily identifiable and retrievable, regardless of whether they are in hard copy or electronic format. A documented procedure should define the controls needed for the identification, storage, protection, retrieval, retention and disposal of records.

Modern x-ray inspection systems offer previously unachievable levels of traceability and enable quick and easy access to relevant information. They offer:

- The ability to perform fast, precise product recalls.
- Enhanced consumer protection and confidence.
- Improved brand building and protection.
- Increased production efficiency and quality control.

Notes

Prevention of Foreign Body Contamination

Detection of contaminants by x-ray inspection systems is one part of an all-encompassing product safety program that reputable manufacturers use to prevent contaminated products leaving their factories. Good practice demands that manufacturers keep the line (and its surroundings) free of contaminants at every stage of the production process.

With specific application to food and pharmaceutical products, this chapter provides practical guidance on how to prevent contamination in the first place.

12 Prevention of Foreign Body Contamination

12.1 Contaminated Raw Materials

The main source of contamination comes from the raw materials used in the production of food and pharmaceuticals. Inspecting raw materials before the production process begins can identify and eliminate many large pieces of metal, mineral stone, glass, calcified bone, dense plastic or rubber, before they become broken into numerous smaller and less detectable pieces.

Large contaminants entering the production process can cause expensive damage to downstream processing equipment as they can harm equipment such as blades or cutters. If these become damaged or broken, this can add further metal shards and other contaminants to the production line, with resulting production downtime.

Inspecting and eliminating contaminants as early as possible during the manufacturing process can also reduce the costs of rejection, since contaminated ingredients are eliminated before further value is added to the product.

For example, a pork pie manufacturer receives 100kg of pork with the bones still present. At this stage of the manufacturing process, the bones are easily detected when x-rayed, so that only small amounts of meat are wasted when the bones are removed.

However, if the raw meat is processed before the bones have been removed, bone contaminants will be fragmented and more widely spread, consequently making them harder to detect. As a result, a larger volume of product will be contaminated and wasted.

If suppliers inspect all raw materials coming into the factory before any processing is undertaken, they can ensure greater control over the quality of in-coming ingredients, which can then be monitored throughout all stages of the manufacturing process.

The best approach is to ensure that suppliers take full responsibility for the quality of their products by operating their own effective x-ray inspection program before supplying the raw materials to the manufacturer.

Supplier agreements or individual ingredients specifications should clearly state applicable operational sensitivity standards, and should also include any other specific precautions that the supplier ought to take, depending on the product type.

12.2 Maintenance Procedures

There's an inherent risk of contamination every time a product is transferred from one process to the next or during a single production process, e.g. breakages of glass jars/bottles on the production line. Crushers, mixers, blenders, slicers, sieves, fillers and transport systems are all typical potential sources of contamination if they are not properly maintained.

There's also the potential for creating contamination when conducting maintenance routines or when performing new installations. The importance of carrying out preventive maintenance under controlled conditions is essential to the effective operation of any x-ray inspection program.

Procedures for maintenance should ensure that:

- Product safety and quality are not jeopardized during maintenance operations and installations.
- A documented, company-wide, planned maintenance program is in place.
- Instructions are available to maintenance personnel indicating what's to be done during planned maintenance (including strip-down and re-build procedures).
- Personnel are trained to follow these instructions. This training should be provided by the equipment provider or by the organization's own staff who have been trained by the provider.
- All outside contractors and engineers receive an induction program so that they are aware of, and adhere to, company manufacturing practices and hygiene standards.
- Arrangements are in place for ensuring that tasks are raised and completed on time - and highlighted if they are not carried out for any reason.
- A full test of all applicable systems is carried out following repairs, maintenance or adjustments.
- Provisions are made for the management of spare parts and replacement equipment.

It's important that potential hazards, such as defective machinery, are reported as soon as identified, so there should be a clear reporting process to relevant responsible personnel. Once such feedback is received, the necessary action must be taken immediately; then, relevant maintenance procedures should be reviewed in order to make appropriate revisions. This process should keep working procedures and practices effective, efficient and thoroughly up-to-date.

12.2.1 Planned Preventive Maintenance Program

The planned Preventive Maintenance (PM) Program should aim to limit wear and tear on equipment that might otherwise result in contamination or contribute to a reduction in equipment efficiency. Total Productive Maintenance (TPM) or Reliability-Centered Maintenance (RCM) are examples of relevant industry-recognized programs designed to achieve these aims. For such a program to be effective, the degree and frequency of the maintenance activity should be based on:

- Plant breakdown history.
- Equipment provider's recommendations.
- Lubrication requirements.
- Importance of equipment in the manufacturing process.
- Risk assessment of critical locations where contamination might occur.
- Equipment known to be vulnerable to wear and tear, e.g. bearings, slicer and mincer blades, mixing vessels, sieves, fillers, etc.

12.2.2 Documentation and Records

Records of maintenance undertaken, as well as any subsequent corrective actions, should be recorded. This information can be used to good effect when reviewing the effectiveness of the planned maintenance program and incident resolution.

The maintenance status should, ideally, be indicated on the equipment itself for maximum visibility. Typically, the information should include the date last checked, who made the check, and when the next check is due.

12.2.3 Good Engineering Practice (GEP)

Pieces of metal such as metal filings etc., are often produced when repairing, modifying or installing equipment – and there's always the risk that metal or other contaminants may find their way into the product and contaminate it. This risk can be significantly reduced when maintenance personnel are trained in safety and hygiene, and when the work is carried out in accordance with good engineering practices.

Listed below are a few examples of what constitutes Good Engineering Practice (GEP):

- Wherever possible, engineering work should take place outside production areas – preferably in the engineering workshop. Welding, drilling, riveting and soldering should never take place on equipment being used in the production process; neither should it take place on any equipment immediately adjacent to production equipment, unless suitable hygienic screening is in place. For major work or new installations, complete floor-to-roof screens may be necessary.
- Workshops should be kept clean and tidy. They should be swept or vacuumed at least daily, with staff demonstrating a clean-as-you-go approach.

- Engineering spares and equipment should be stored off the floor to enable access to all floor areas for thorough cleaning.
- Equipment used within the workshop should be maintained in a good working condition and subjected to the same regular cleaning.
- Any equipment that's been maintained or repaired in the workshop should be thoroughly cleaned to remove all debris. The appropriate method should be used to undertake this process (e.g. magnets, vacuum cleaners, etc.) before equipment's returned to the production area.
- If the workshop is within the production environment, a suitable foot-scraper mat (or other similar trap) should surround the workshop, accompanied by a clear note which requests staff to scrape their footwear before leaving the workshop.
- Personnel carrying out repairs on production lines should be provided with an enclosed tool box for tools, nuts, bolts and screws, etc. Production packaging should never be used to store parts or machinery components.
- No wooden-handled tools should be allowed into the production area, and magnetic trays should be used to secure magnetic fixings. Non-magnetic fixings (e.g. rubber seals or washers) which have been removed or replaced during engineering work should be stored in clearly-marked containers.
- Tool boxes should be kept clean and free of any unnecessary content which could be hazardous to production.
- Once repairs, installation and commissioning have been completed in the production area, the equipment and the surrounding area should be independently inspected to confirm that cleaning has taken place in accordance with agreed procedures. Appropriate documentation should confirm that designated personnel have checked whether production lines are clean and that production can restart.
- Tape or wire, by way of temporary engineering solutions, shouldn't be used to repair equipment. Damaged fittings and missing or loose screws should be repaired promptly and permanently. Any metal debris, along with other potential contaminants, should be disposed of safely and promptly. Missing fixings on equipment should be accounted for and/or replaced. Nylock nuts, or similar secure items, should be used in preference to other types of fixings.
- Wherever possible, nuts, bolts, seals, connectors and washers, sieve mesh, etc. used on processing equipment should be made from high-density materials.

12.3 Good Manufacturing Practice (GMP)

Personal effects and operational consumables present a real contamination risk if there's poor awareness and lack of good working practices. Time spent identifying potential risks, defining good working practice, and providing the correct equipment, will be rewarded by minimizing the risk of contamination. Clear and concise policies should be implemented and communicated on a regular basis to ensure that personnel remain informed and supportive of contamination-reducing regimes.

Listed below are just a few examples of what could constitute Good Manufacturing Practice (GMP). There are, undoubtedly, many more control measures that are relevant to specific industries, companies and manufacturing processes – and this list demonstrates risks that could easily be overlooked:

- Paper clips and staples shouldn't be used on documents in production areas.
- Pins shouldn't be used on noticeboards.
- Hair clips, watches, jewelery, etc. shouldn't be allowed in production areas.
- Protective clothing should have no outside pockets.
- Only 'x-ray detectable' plasters or wound dressings should be used by personnel, to aid detection if lost in production processes. While metal-detectable plasters contain plastic material made conductive by carbon 'doping', x-ray detectable plasters contain strips of high-density tungsten. This makes the plasters both metal-detectable and x-ray detectable.
- Only 'x-ray detectable' pens and ancillary equipment should be used by personnel, to aid detection of lost items.
- Product-holding containers should be covered at all times.
- Conveyor lines carrying open cans or glass jars should be covered until the containers are filled and closed, or capped.

Notes

Selecting the Right Critical Control Points (CCPs)

Adherence to the Hazard Analysis and Critical Control Points (HACCP) process is the surest way to keep food products free from contaminants. HACCP firstly identifies potential sources of contamination and then identifies the inspection points at which it will be easiest to secure and remove contaminants.

For each Critical Control Point (CCP), there's an appropriate detection solution provided by an x-ray inspection system.

This chapter provides practical guidance as to where to use an x-ray inspection system on the production line.

The Seven Principles of HACCP

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 action
6. Establish record-keeping procedures
7. Establish procedures to verify that the system is working as intended

13.1 Conduct a Hazard Analysis

Every manufacturer should perform a Hazard Analysis for every product they produce; this procedure will assess the risk of contaminants being present.

A Hazard Analysis requires that all hazards which may reasonably be expected to occur (including hazards associated with the processes and facilities used) should be identified and assessed. Potential sources of foreign body contamination also need to be identified.

For example, if a producer makes snack/cereal bars, the Hazard Analysis may show a potential risk from:

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

This is a simple example, illustrating that different types of contaminants can cause potential contamination at different stages of the production process.

X-ray inspection is a popular control process used in those areas where physical contamination hazards are an identified risk. If a specific type of contaminant occurs frequently, this should be highlighted as soon as possible (together with all other relevant information) as this will have a bearing on the most suitable type of x-ray system for the application.

13.2 Identify Critical Control Points (CCP)

When determining CCPs, consideration should be given to identifying and rejecting the contamination as soon as possible within the manufacturing process. HACCP doesn't rely solely on end-product testing to ensure that food is safe; instead, it builds food safety into the manufacturing process, and relies on process controls to prevent or reduce the presence of known hazards to an acceptable level within food or pharmaceutical products.

If contamination is knowingly allowed to travel through the manufacturing process, there's a danger that it may cause damage to downstream processing equipment – or it could break into smaller pieces, making it more difficult to detect further down the production line. This could result in unnecessary product reject costs due to:

- The higher volume of product contaminated.
- The value that's been added to the product at this late stage of the production process e.g. packaging.

Some food and pharmaceutical processors may use a single x-ray system off-line, to make random checks or to inspect suspect or quarantined product. However, inspection requiring additional handling is never totally secure – and, whenever possible, the x-ray inspection system should be integrated in-line with the normal production flow. This avoids possible confusion over what's been inspected and also prevents any bypass of the inspection process.

An x-ray system should be installed as close as possible to the source of contamination; however, as a minimum requirement, the end of every production line should be considered as a CCP. Once the product's in a sealed pack at the end of the packing line, the potential for contaminant inclusion afterwards is significantly reduced.

13.3 Establish Critical Limits for each CCP

Having identified the CCPs, it's important to define the 'Critical Limits'. Critical Limits are specified safety limits at CCPs, which separate acceptable (safe) food from unacceptable (unsafe) food. Critical Limits are usually numerical values based on scientific findings.

A qualified person should install the equipment to ensure that:

- Sensitivity is optimized.
- False rejects are minimized.
- Critical Limits are both achievable and repeatable.

In the case of X-ray inspection systems, Critical Limits relate to:

- The operating sensitivity (Chapter 14).
- The operation of the reject mechanism (Sections 4.4 / 16.1.5.7).
- Inbuilt failsafe features (Sections 5.13 / 16.1.6).

Chapter 6 of this guide explains the factors limiting sensitivity, while Chapter 14 explains how to define and document the actual operating sensitivity standard.

13.4 Establish CCP Monitoring Requirements

Monitoring procedures need to be established to ensure that hazards are controlled at CCPs.

Having established the operating sensitivity limits, it's important to periodically verify the ability of the x-ray inspection system to detect and reject contaminated product at, and above the operating sensitivity standard. Chapter 16 of this guide provides practical guidance on how to define the appropriate test and audit routines; it also discusses best-practice record-keeping procedures.

13.5 Establish Corrective Action

If the monitoring process reveals that the CCP is not operating to the agreed critical limits, there needs to be a clearly-defined process for corrective action. Chapter 17 of this guide provides guidance on what actions should be taken in the event of a fault with the x-ray inspection system or when contamination or non-uniform product is detected.

13.6 Establish Record-Keeping Procedures

A HACCP-based system must have appropriate documentation to demonstrate that it's working effectively. This documentation will usually incorporate HACCP charts, work instructions, written procedures/policies, training records, monitoring records, sampling records, invoices, and receipts, etc. (See Section 11.3).

13.7 Establish Procedures to Verify That the System Is Working as Intended

This involves taking an overview of the HACCP-based system to ensure that it's working effectively. Checks already carried out need to be re-checked to ensure that they are true, and that they are effective at controlling hazards (see Section 15.4).

13.8 References

Links to various sources and types of information are included below for reference:

Dutch HACCP (ISO 22000)

http://www.foodsafetymanagement.info

HACCP Principles Side by Side

http://www.fsis.usda.gov

US FDA HACCP Guide

http://www.fda.gov/Food/GuidanceRegulation/HACCP/

WHO / CODEX HACCP

http://www.who.int/foodsafety/fs_management/en/intro_haccp.pdf

Notes

Operating Sensitivity

The factors that affect detection sensitivity have been discussed in Chapter 6 – but it's also important to understand how to establish sensitivity standards that are appropriate to each individual application, i.e. sensitivities that are optimal for consumer protection and production efficiency. These sensitivities should be set at a level that avoids false rejects, so as to save costs, as well as be sufficient to ensure outstanding contamination detection in order to protect the end consumer.

14.1 The Need for Maximum Operating Sensitivity Performance

Ideally, x-ray inspection systems should be set for maximum sensitivity performance with a minimum false reject rate; this should provide optimum consumer protection and maximum line efficiency. The overall aim should be to consistently improve contamination capabilities wherever possible.

Operating sensitivities imposed by external organizations (such as retailer and consumer brand codes) should always be considered as the minimum acceptable standard. If more stringent standards can be practically applied, this should be regarded as Good Manufacturing Practice (GMP) (see Section 12.3).

It's important that the x-ray inspection system is able to deliver long-term, effective and reliable inspection at the programmed operating sensitivity; otherwise operators will lose confidence in the inspection solution, and there may be a tendency to turn down the sensitivity setting to avoid false rejects.

14.2 Establishing the Operating Sensitivity Performance

The best attainable sensitivity will usually be dependent upon product texture and density, so the sensitivity level should be selected in consultation with the x-ray system's technical representative.

When determining operating sensitivity (or when comparing capabilities of different x-ray inspection systems), it's important that:

- The x-ray inspection system has minimum false rejects arising from variations in product and packaging.
- The sensitivity performance is maintained permanently, without the need for regular operator checks.

Optimum detection sensitivity should be established and set for each product to be inspected; it's best to start with the system set as close as possible to optimum sensitivity levels.

This setting is normally established after performing an initial product auto-learn procedure (see Chapter 8), although most advanced modern x-ray systems also have the choice of high, medium or low auto-sensitivity settings.

It's essential to pass a quantity of non-contaminated products through the x-ray system; if any of these 'good' packs are falsely rejected, sensitivity should be reduced to avoid any further false rejects.

Records of sensitivity set-up trials, and results for each product, should be retained for review during technical and hygiene audits.

Sensitivity adjustment controls should only be accessible to specially trained and individually-nominated employees. Access by other employees should be prevented by means of password protection or by locking adjustment parameters.

14.3 Establishing a Sensitivity Standard

Manufacturers should balance the desire for maximum operating sensitivity performance against the practicalities of implementation and enforcement. For food and pharmaceutical manufacturers, it's not always feasible to set a very high level of detection sensitivity (which then causes a high false reject rate), because production efficiencies can be badly affected as a result. The performance level should be based upon risk assessment and is, ultimately, the decision of the manufacturer.

The sensitivity standard is usually set at one or more of the following levels:

- Company-wide.
- Product group/production line-specific.
- Product specific.

Company-Wide Sensitivity Standard

It's normal for producers to apply a common company standard across many different production lines and products. It's also normal for producers to apply a common company standard across different x-ray inspection systems sourced from various providers.

The disadvantage of this approach is that sensitivity may not be maximized for a given application or product. In addition, the company standard is likely to be dictated by the lowest common denominator, i.e. the worst sensitivity performance or the least efficient x-ray system.

Agreeing to a minimum company-wide sensitivity standard for finished pack inspection will help overcome the possibility of an x-ray inspection system being installed at the wrong place in a production line, e.g. the inspection of finished cases instead of the inspection of each individual pack.

The sensitivity normally achieved on a small individual pack detection system (typically 1.5mm stainless steel or better) is unlikely to be achievable on a case inspection system, due to the size of the aperture and the increased depth of inspection (see Chapter 6).

Product Group/Production Line Sensitivity Standard

It's common practice to define the sensitivity standard at a product/group level or for individual production lines, where the products are similar.

Defining sensitivity standards at product group and/or production-line level may give assistance in identifying poorly-performing x-ray inspection systems.

Product-Specific Sensitivity Standard

In order to maximize operating sensitivity, consideration should be given to defining sensitivity standards at product level – and ideally, the number of settings for different products should be kept to a minimum. The more options available to an operator, the more likely it is that a mistake will be made in selecting the correct product settings.

14.4 Documenting the Sensitivity Standard

The sensitivity standard should be expressed as the minimum detectable sample size. This should be denoted by the nominal spherical sphere diameter and the material type, e.g. 1.5mm diameter stainless steel.

The sensitivity standard should be formally documented (issue control and authorized) and effectively communicated throughout the organization. It should be readily available to appropriately trained personnel.

Where an x-ray inspection system is employed for the detection of metal contaminants, as well as for other dense contaminants, the x-ray system must meet the same metal detector sensitivity standards for the detection of such metal contaminants. In addition, sensitivity standards can be set for other non-metallic contaminants, such as mineral stone, calcified bone, glass, and high-density plastic and rubber compounds.

Installation, Commissioning and Training

The location and surroundings of an x-ray inspection system can affect performance – and this chapter deals with those environmental factors that hinder or support successful installation.

By ensuring that all matters relating to the x-ray system are correct right from the start (including appropriate training), manufacturers are far more likely to see the benefits of a successful and long-lasting x-ray inspection system.

15.1 Installation

The intended location and environment of the x-ray system installation could, potentially, have an adverse effect on the system's operational performance. To ensure the best possible results, the installation instructions issued by equipment providers should be consulted before and during installation; this will ensure that the best possible performance is obtained from the system, while minimizing risks of operational product-handling problems or false rejections.

System provider instructions will contain more information than this guide can provide; however, general principles can be applied to most x-ray inspection systems, and gaining a basic understanding of these principles will help at the time of equipment selection, at the specification stage, and at the actual installation. The basic guidance is as follows:

Equipment Access

Equipment should be positioned to give clear access from all sides, for ease of:

- Cleaning – air-conditioning filters, conveyor belt, transport assembly, reject receptacles and floor area around the machine.
- Servicing – electrical cabinets, pneumatic controls and conveyor assembly.
- Operation – touch-screen interface, reject receptacles, general access hatches and sufficient space for cooling.

Vibration and Mechanical Shock

As far as practically possible, x-ray inspection systems should not be installed in areas that are subjected to, or near, vibration and mechanical shock. Where this can't be avoided, every effort should be made to minimize such effects.

Good practice is to hard-fix the machine's feet to the factory floor. For health and safety reasons (and because of vibrational effects), the use of casters or wheels is not recommended, particularly on large or top-heavy x-ray systems.

Electromagnetic Interference

Radiated electrical noise generated by surrounding electrical installations may adversely affect the performance of a system, to a point where the system exhibits erratic operation (e.g. false rejections). Variable Frequency Drives (VFDs) positioned near the detector should be installed in accordance with the provider's instructions.

Where possible, anti-static conveyor belts should be used; furthermore, cables from inverters, variable-speed drives, etc. should be shielded and should not be located close to the detector set or detector cables.

Most x-ray providers now offer comprehensive EMC (Electromagnetic Compatability) testing certificates.

Clean Power Source

Power cable noise may arise from significant changes in the loading of the electrical mains that feeds the system, so it's good practice to have current-suppressors/filters fitted in-line to clean the electrical mains supply. This is particularly relevant for x-ray inspection systems that use encoders or tacho signals.

Installation Compliance

All aspects of x-ray system installation should satisfy the relevant legislation applicable to the country in which the equipment is installed. For example, depending on the country of installation, tunnel guarding may need to be extended on the x-ray system, to ensure that local radiation safety standards are met.

It's also recommended that the installation of x-ray inspection systems is carried out only by qualified service engineers.

Installation in most countries will require a critical radiation survey on the machine, once it's been installed and is running. This needs to be undertaken by a qualified person at Radiation Protection Supervisor (RPS) level. The role of the RPS on site is to make regular checks on the machine, to maintain records, and to ensure that the testing equipment is calibrated and working correctly. The RPS also acts as the point of contact for any x-ray safety questions.

15.2 Commissioning

Prior to normal production use, the installed x-ray system should be commissioned to ensure that:

- The system physically operates as intended, with regard to factors such as set-up product menus, belt speeds and reject timings.
- The system meets the required specification for inspection e.g. sensitivity of detection, mass measurement, fill level.
- All relevant personnel are trained in its safe and correct use.

Table 15.1 shows a checklist of items to consider during x-ray system commissioning.

Checklist	
Equipment and support documentation has been correctly supplied	✓
Installed equipment is in a satisfactory condition	✓
Equipment has been satisfactorily installed	✓
Equipment meets the customers specifications for product integrity inspection	✓
Operators have been trained to a minimum basic level (operation, care and maintenance)	✓
Equipment for regular checking of the machine is on site, calibrated and functional e.g. radiation meter	✓

Table 15.1

15.3 Training

A trained engineer (or representative from the original equipment provider) is the recommended individual who should carry out the required commissioning process. Experience gained in other installations will help such an expert to identify potential problems as soon as possible, allowing for implementation of corrective action at the time of commissioning.

Documented evidence should demonstrate that all key aspects of the installed x-ray inspection system have been satisfactorily qualified before operational use. This should be considered specifically in relation to the actual installation location and surrounding environment.

Re-qualification of the installation should be considered, if there is a significant change in, or around the installation, or if the equipment is moved to a different location (this is particularly relevant to emissions).

The operational aspects of the x-ray inspection system should be re-qualified before running new or revised products through the existing installation. Documented evidence should be generated to demonstrate that this has taken place.

Most x-ray providers will have a pre-set training program to cover each level of operation required.

15.4 Maintenance and Performance Verification

It's important to ensure that the equipment is correctly maintained throughout its service life, so that it can operate at optimum performance with maximum uptime. A Preventive Maintenance Program (see Chapter 12) ensures that future mechanical or electrical problems can be addressed before a breakdown occurs.

This should include regular maintenance, as well as performance verification checks of the x-ray inspection system by a trained person. Such a process should typically take place once every 6 to 12 months. Ideally, the verification process should be carried out by a trained engineer in accordance with an agreed service contract.

The qualification packages available from x-ray system providers can aid in the development and scheduling of a routine Performance Verification Program (see Chapter 16 for further details).

Belt Maintenance

Substances which can be detected by the x-ray inspection system (e.g. metal fragments, thick adhesive labels, stones, etc.) are likely to cause unexpected detections if they adhere to the conveyor belt. Their presence often gives the appearance of erratic or incorrect operation. To minimize the chance of this occurring, the following points need to be considered:

- Repairing/construction operations in the vicinity of the conveyor belt (such as welding, metal drilling and cutting) should be avoided, since these could cause metal fragments to come into contact with the belt.
- Belt-scrapers can be fitted.
- Conveyor belts should be cleaned regularly.

15.5 References

Links to various sources and types of information are included below for reference:

Health Protection Agency (UK)

http://www.hpa.org.uk/radiation

Notes

Performance Verification and Auditing

Over time, most machinery tends to 'drift' in terms of performance – in other words, it loses its original precision and accuracy. X-ray inspection equipment is no different – so, from time to time, it needs to be brought back in line with its original operating parameters.

This chapter outlines procedures for ensuring that x-ray equipment operates within these proper limits so that it can maintain correct detection rates and keep false reject rates at an optimal level. This chapter also describes testing procedures – and how often they should be undertaken, as well as the documentation required to demonstrate that the correct levels of risk management have been complied with.

16.1 Installation

Every x-ray inspection system should be periodically monitored to demonstrate correct risk management procedures, and to ensure that:

- It continues to operate in accordance with the specified sensitivity standard.
- It continues to detect contaminants correctly.
- It continues to detect product defects, e.g. missing product, underfill/overfill and mass.
- All additional warning/signaling devices are effective, e.g. alarm conditions, reject devices and emergency stops.
- Installed failsafe systems are functioning correctly, e.g. reject confirmation, 'bin full' warning and low air-pressure sensor.

The verification and audit procedure should ensure proper compliance with:

- Company standards.
- Line standards.
- Product sensitivity standards.
- X-ray inspection policy.

Verification and audit procedures should be documented and communicated to all relevant staff, especially those responsible for conducting necessary verification procedures and audits. As a minimum level for contamination detection, procedures should cover:

1. Test sample types to be used
2. Positioning of test samples in the pack

3. Effective use of test packs (where applicable)
4. Frequency of testing
5. Number of tests
6. System calibration and reject device test methods
7. Failsafe systems testing
8. Treatment of rejected/suspect product (see Chapter 17)

16.1.1 Test Sample Types to be Used

When determining whether the x-ray inspection system is still detecting in accordance with expected levels of detection, the verification test makes sure that there's been no significant loss of sensitivity since the last verification test.

Loss of sensitivity can occur as a result of manual changes in software settings, or as a result of the 'drifting' of electrical/mechanical components over time. Repeated usage can also result in loss of sensitivity.

Certified stainless steel and glass spheres are, typically, used during verification tests because the density of these objects can be reliably measured. To ensure accurate results when using glass test samples, the density of the glass sample should already be known – and it should be compared to the density of the container glass being used on the production line.

Problems may arise if:

- A high-density glass sample is used for testing, since it may contain traces of lead.
- The actual production-line jars and bottles (which are likely to be the main source of glass contamination) are made from lower-density glass.

In this case, the glass test piece would be detected, but the container glass would not. This would generate a false and unreliable result; so, good practice is to use production-line glass samples for testing on glass-in-glass x-ray inspection applications.

Regardless of any guidance provided, there's no substitute for in-plant knowledge and carrying out tests on the actual product. From prior risk assessments, the types of potential contaminants within the manufacturing facility should already be known – and from these facts, the following questions should be answered:

- Which contaminant types are the hardest to detect?
- Where is the worst-case detection position for each given contaminant? (this is more relevant for non-uniform products).

This information will help to produce the most effective verification test method for any given application. Ultimately, the contamination tests should either satisfy external customer or retailer codes or they should comply with company-specific policy/test requirements.

Ideally, test samples should be placed within the product or should be securely attached under the base of the packed product.

Test samples should consist of a precision-manufactured sphere placed within a sealed, low-density carrier. This arrangement ensures that only the test sphere – and not the carrier – will be imaged on the x-ray system. Different test materials and sizes are available to represent potential sources of contamination.

Test samples should be certified and permanently marked with the size, material and batch-specific reference number. This allows for efficient traceability to the original producer's manufacturing lot.

Suppliers of certified glass test spheres should accompany each test piece with a certificate, containing:

- The sample reference number.
- The tolerances on the nominal diameter.
- The material of the final component.
- The specific gravity of the glass.

The verification procedure should fully define the test samples to be used, including the actual material type and size used. Test samples should be visually inspected before use, to ensure that they remain fit for purpose. If there's any doubt over the integrity of the test sample, it should be replaced.

16.1.2 Positioning of Test Samples

Since a test sample is used to challenge the level of detection currently achievable, the factors which affect sensitivity relate directly to the final quality testing procedures which are set and implemented.

Factors affecting sensitivity have already been discussed in detail in Chapter 6, and these are the basis for a recommended conclusion or best-practice guidelines for positioning test samples.

Outside or Inserted in the Product

Apart from bulk-flow applications, most products are presented to an x-ray system in a format greater than 30mm in depth, which means that there's a negligible difference between a test sample placed outside a product, and a test sample inserted in the product. Therefore a test sample doesn't need to be inserted in the pack; it can be attached to the pack.

Position in the X-ray Beam

There are different theories on test-sample positioning. Recent studies have suggested that the effective position of the test sample in the beam has little or no impact on the level of detection achievable. There are so many variables that one recommended position of placement is not possible. Variables include:

- Product depth.
- Product texture.
- Type of packaging.
- Diode size.
- Focal distance.
- X-ray power levels.

To cover all possible eventualities, recommended good practice is to make a minimum of two tests on all packaged products:

1. Test 1 – using a calibrated sample placed as close as possible to the x-ray source
2. Test 2 – using a calibrated sample placed as close as possible to the detector

On a vertical-beam (down-shot) x-ray system, a test sample is placed on the top of the pack and subsequently under the base between the pack and the belt surface.

On a horizontal-beam (side-shot) x-ray system, a test sample is placed on the side of the container facing the source, and then on the side facing the detector.

Good practice on irregular packs (e.g. a poly-bag of loose, randomly-placed product) is to position the test card in several locations:

- Under the product.
- In voids between the product.
- On the edge of the product – this is particularly important, since it can be the most challenging detection location.

16.1.3 Effective Use of Test Packs

Test packs are commonly used on packed product inspection lines.

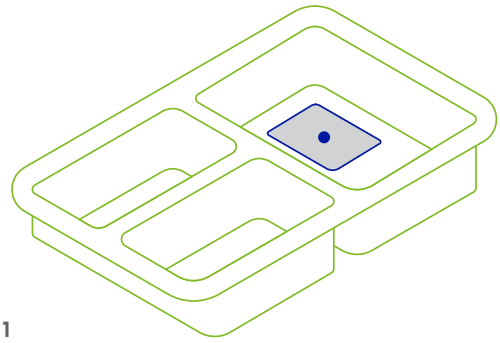

Figure 16.1

When test packs are used, it's important that the following requirements are defined and contained within the test procedure:

- The method of validating that the packs are free from contamination before inserting/attaching test samples.
- The method of making up the test pack, including the position/location of the test sample within/on the test pack.
- The frequency at which the test packs should be made up – so as to reflect the nature, durability and shelf-life of the product.
- Test packs should be representative of the production batch. Ideally, they should be freshly made up for each new production batch, since the aging of the product may affect its texture and so will not be representative of the actual product being manufactured.
- The method for labeling the test packs, so that they are not accidentally put into the supply chain e.g. marking with colored tape.

16.1.4 Frequency of Testing

Procedures should clearly state when verification testing should be performed within the manufacturing cycle. Consideration should be given to implementing verification testing at the following stages:

- At the start and finish of daily production/shift.
- At regular intervals during the production run, typically hourly.
- At changes of production batches.
- At changes in machine settings.
- After repair downtime.

Considerations for each of the above stages are defined below.

Start and Finish of Production/Shift

As a minimum, verification testing should be made at the start and end of the production/shift to ensure that the x-ray inspection system detects and rejects in accordance with the sensitivity standard. The testing should also ensure that any additional warning systems are functioning correctly, e.g. reject 'bin full' indicator.

However, there can be a problem when testing at this interval: if the verification test fails at the end of the shift, the entire batch produced during that shift must be quarantined and re-tested.

In addition, if there are any failsafe features which have been included as part of the system specification, these need to be validated at the start of each shift (see Section 16.1.7). If a failure is observed, it should be corrected before starting the daily production/shift.

Regular Intervals During Production Run

Since the frequency of verification during a production run is application-dependant, the time between verifications should be defined within the procedure. There's a balance to strike between production efficiency and the compromising of that efficiency through interruptions caused by quality checks. Ultimately, the intervals between verifications during a production run will depend upon the probability and consequences of a failed test. The following factors should be taken into account:

- Quarantine period.
- Customer, retailer and consumer brand codes of practice (if applicable).
- Failsafe system design.
- Monitoring reject rate.

Quarantine Period

The quarantine period relates to the time taken to produce the maximum amount of product stored on the company's premises before it's shipped. The verification period should be shorter than the quarantine period. In the event of a test failure, the product manufactured since the last successful verification will still be on the company premises, and so it can be easily identified and isolated before further action is taken (see Chapter 17).

Customer, Retailer and Consumer Brand Codes of Practice

Customer, retailer and consumer brand codes of practice may well specify a frequency of verification greater than the quarantine period.

Failsafe System Design

Robust failsafe system design and access control can be used to good effect in reducing the probability of a failed test, and therefore reduce the frequency of testing. For example, if production-line operators are restricted from making setting changes (e.g. adjusting sensitivity by means of access control), the potential for a verification test failure is reduced.

Monitoring Reject Rate

If too many rejects are confirmed within a specified period (i.e. five consecutive products rejected), this prompts a stop alarm.

Changes of Production Batches

Consideration should be given to performing a verification test to confirm that detection and rejection rates match the probability of detection. This should be done whenever there's a change in product type running through the x-ray inspection system.

Changes in Machine Settings

A verification test should be performed to confirm that detection and rejection rates match the probability of detection whenever there's a change in the x-ray inspection system settings.

After Repair Downtime

If maintenance work or repairs have been carried out on the production line during downtime, the x-ray inspection system and reject mechanism should be re-validated when production re-starts.

16.1.5 Number of Tests

The number of tests to be performed should be derived from the knowledge of machinery performance established during the original commissioning activity. During this original commissioning procedure, the capability and performance levels of the x-ray inspection system will have been established.

The x-ray inspection system should be tested at the limit of detection. This type of testing should be able to identify a drop in performance as soon as it occurs.

Three tests per test sample material would be considered the maximum practical level for production verification purposes. In theory, where good detection capability has been established during commissioning, one test per test sample of material would be sufficient. However, at least two tests should be carried out (e.g. one stainless steel, one soda-lime glass), so as to challenge the scenario of 'consecutive' rejects, where two consecutive packs are close to each other. This two-test process ensures that the reject system works effectively and correctly.

Ferrous metal, non-ferrous metal and stainless steel all have very similar densities, so a single test sphere (usually stainless steel) will suffice for all three materials. Normally, stainless steel and soda-lime glass are the only test sample materials used, as they can be properly quantified.

The number of tests to be performed for each test sample material will depend on the statistical requirements of the producer and the demands of external agencies.

16.1.6 System Calibration and Reject Device Test Methods

Verification procedures should include precise details of the methods to be used. The methods will vary in accordance with the x-ray inspection system design and the actual application.

Testing the correct function of the reject device confirms that it's still capable of rejecting the contaminated, damaged or missing product that the system has identified. For example, testing could identify that the air supply to an air-blast reject device has become disconnected, resulting in failure to reject contaminated product.

However, it's more efficient to devise a test method for the entire x-ray inspection system at the same time, so that it tests both the detector and the reject device as part of the same process.

For the test to be successful, all the test packs/test samples should firstly be detected, and then they should be rejected into the correct reject receptacle, where they should be kept. If any part of the verification test fails, product manufactured since the last satisfactory test should be isolated and re-screened using a functioning x-ray inspection system (see Chapter 17).

Testing Conveyor Systems with Discrete Products or Packs

The test samples should be randomly placed under and on top of the test packs; they should then be passed down the production line and through the x-ray inspection system, one after another. This ensures that the x-ray inspection system can detect and reject contaminated product, regardless of the position of the contaminant or its distribution throughout the production line. Precautions should be taken to ensure that non-rejected test packs or test samples don't become incorporated in the production flow.

With the conveyor set at the normal production-line running speed, all test packs should be placed on the production line. The spacing between the packs should be the normal distance between products which travel down the line.

For a belt-stop alarm system, each individual pack should be passed down the line. For the test to have been successful, the test pack should be detected and the conveyor stopped. It should only be possible to re-start the system after the x-ray inspection system has been re-set.

The test sequence should be repeated for the specified number of tests. As discussed previously, the types of contamination to be tested, and the number of tests to be performed, depend on a range of factors, and there needs to be a sensible, practical balance between production-line efficiency and contamination detection. Ultimately, this balance between frequency of testing and interruption of production depends on the level of risk that the company's prepared to take.

Testing Conveyor Systems with Bulk Product

Test samples should be directly fed into the product flow via the in-feed mechanism (such as a hopper feed), and the test sequence should be repeated for the specified number of tests. Precautions should be taken to ensure that test samples will not be lost if they are not detected/rejected, especially if the product is fed directly into another processing machine after the x-ray inspection system.

Testing of Pipeline Applications (Liquids, Slurries and Pastes)

For pipelines containing liquids, slurries and paste products, test samples should be placed at random in the product flow. The reject device should then be observed to see if it successfully diverts the test samples to the reject position. Test samples should be encapsulated in a material of a different color to that of the product, making them easily identifiable in the rejected product.

To verify that the reject timing is correct, the test piece should be located in the center of the rejected product. The test should, typically, be repeated three times.

The system will have to be tested externally where there are pipelines containing liquid products; the same applies to aseptic pipeline systems. Where it's not possible to reject test samples into the air (or to install a system to catch the test samples if they fail to be detected), the system will have to be tested externally (see Section 4.1.3).

Testing Glass Jar / Bottle Inspection Systems

Jars or bottles containing test samples are differentiated from normal products by being fitted with a different colored lid. There are various internal areas of the jar that could contain contaminants, so the detection of contaminants in these locations needs to be verified.

Figure 16.2 shows four locations in a glass jar where detection is most difficult. Ideally, a test sphere should be placed in each of these areas to ensure a thorough testing; however, in practice, it's not always possible to make up such complex test jars. For this reason, packers of products in glass containers should undertake preliminary checks of each jar, covering the corner of the base and the side walls in the body area.

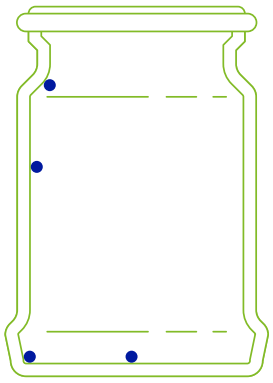

Figure 16.2

A number of test sample jars should be produced, each containing a different contaminant at a different location within the jar. All the jars should then be fed into the production line to verify that the system is successfully detecting and rejecting contaminants to the agreed specifications. The test procedure should be repeated at the agreed time intervals during production, typically every 30 or 60 minutes.

Testing Can Inspection Systems

Glass container and canning lines often operate at very high speeds. To verify that an x-ray inspection system is performing at the required levels of detection, the line needs to be stopped. Test sample cans should then be passed through the x-ray inspection system to verify that the system is detecting and rejecting contaminants in accordance with the agreed specifications (Figure 16.3).

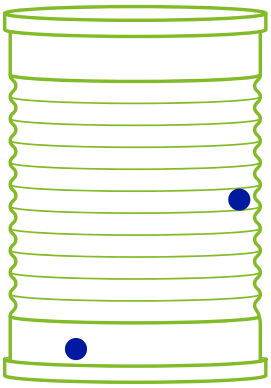

Figure 16.3

Product Rejected During Normal Verification Testing

If good products are falsely rejected during normal test procedures, they should be re-introduced into the product flow for re-inspection, upstream from the x-ray inspection system.

16.1.7 Failsafe Systems Testing

A test method should be established for each failsafe system built into the x-ray inspection system.

The following examples show common failsafe devices which may be incorporated into the x-ray inspection system design and associated test methods.

Challenging Reject Confirmation

Testing should be carried out by passing a test pack down the line, while temporarily interrupting the electrical supply to the reject device solenoid (via a key switch). It should then be observed that the reject mechanism does not operate, that the reject confirmation photocell is not broken – and that the conveyor belt then stops.

During the initial set-up of this test, a record should be kept of where the test pack comes to rest. If the rest position is not on the x-ray system belt, the relevant downstream conveyor should be linked to the 'stop' circuit of the x-ray system. This ensures that all contaminated packs are easily retrievable for investigation following a production-run system failure that has resulted in a belt stop.

Challenging 'Bin Full' Warning

This should be checked by a forced obstruction of the photocell beam within the reject bin. Well-designed reject bins incorporate a small plate next to the photocell within the bin. When manually turned, the plate moves into a position that blocks the photocell and triggers the 'bin full' warning mode.

Challenging Low Air Pressure

By simply turning off the air supply to the machine, the low air pressure fault condition should be activated.

16.2 Product Integrity Testing

In addition to contamination detection, an x-ray inspection system can simultaneously check many other product and packaging defects (see Chapter 8).

Test packs should be made to challenge these inspection routines, and the same guidelines for contamination detection testing should be followed (where applicable), as covered in Sections 16.1.4 to 16.1.7 of this chapter.

Examples of these types of test packs include:

- A can with a low fill of soup.
- A box of confectionery with one chocolate missing.
- A pack of wound dressings with product trapped in the seal of the paper envelope.

16.3 X-ray System Provider's Audit

When audits of x-ray inspection systems are carried out by trained service engineers, these can provide an additional, valuable service in supporting the overall x-ray inspection program. Such tests prove that the equipment complies with the provider's recommendations and good practice; furthermore, experienced x-ray inspection experts can often spot potential problems before they become apparent to the user.

16.4 Performance Verification Routines (PVR)

An x-ray inspection system with a built-in performance verification routine encourages regular testing and record generation. Most standards now require routines that automatically request a test after an agreed pre-set time interval.

The approved test operative enters a user login code into the system so that the test can be completed with the correct test samples. Hard copy documentation (proving tests have been carried out) can be provided through a local printer. Alternatively, if the x-ray system has network connectivity capabilities, records can be downloaded to a USB or central PC using Ethernet communications or OPC connectivity (see Chapter 21).

16.5 Test Results

The results of tests should be documented to demonstrate that all requirements of the verification procedure were executed. These records should include:

- The x-ray inspection system's unique identification reference, e.g. serial number, CCP number.
- Product being produced.
- Date and time of test.
- Test samples used.
- Name of the person who conducted the test.
- Test results for both detection and rejection.
- Test results for any failsafe devices.
- Fault details and corrective action taken (as applicable).

Should any verification test (or part of a verification test) fail, the cause should be immediately investigated and rectified before production re-starts. Product manufactured since the last satisfactory test should be regarded as suspect, and treated accordingly. The details of the fault (and subsequent corrective action) should be recorded as part of the test record.

The accurate recording of test results is extremely important. In the event of a customer complaint or audit, a manufacturer may need to rely on these records to prove that procedures were correctly followed and that the x-ray inspection systems were functioning correctly to the agreed probability-of-detection levels. See Table 16.1 for an example of a typical record sheet.

16.6 False Reject Rates (FRR)

There is a direct relationship between sensitivity of detection and the False Reject Rate (FRR). The more sensitive the inspection settings on the machine, generally the higher the FRR will be, since smaller natural changes in the x-ray image are outside acceptance parameters. Note that false rejects are sometimes referred to as 'false positives'.

Many manufacturers do not regard damaged or deformed packs as false rejects because they are deviations from a 'good pack'; therefore these are classed as rejects.

Additional deviations from the 'good pack' that x-ray manufacturers do not class as a FRR include:

- Rejects caused by the wrong product being passed before the product menu has been changed.
- Product not learned correctly during the set-up process.
- Poor pack presentation due to guide rails not being adjusted correctly.
- Products manually being placed onto the production line, eliminating a suitable gap between products.
- Fallen products, such as a glass jar fallen over before inspection.
- Back-ups caused by downstream blockages or machine stoppage, caused by a factor external to the x-ray system.

If the natural variation in physical characteristics of both the packaging and contained product do not vary from what is determined to be a standard 'good pack' and providing the packs are presented in a stable condition, with correct spacing and lane centers as outlined by the x-ray supplier at the point of sale, the x-ray supplier will be able to optimize the system so that the FRR is at a minimum, and within the customer's acceptable limits.

X-ray Inspection System Verification Record

System Identification					Product		
Date	Time	Test Sample	Detection Test	Rejection Test	Failsafe Test	Corrective Action	Tested By

Table 16.1

Dealing with Suspect and Rejected Product

Every rejected product should be regarded as contaminated and must be treated accordingly, with no risk of it being mixed with good product.

However, every rejected product has a positive value, providing useful information about the manufacturing process, especially:

- The performance of the x-ray system.
- The performance and condition of the production line.
- The quality of the ingredients.
- The safety of the batch.

As a key diagnostic tool, a rejected product should be handled in a manner that helps production staff to find out what caused the product to be rejected.

Only trained and authorized personnel should have access to rejected product – plus they should have the knowledge and capabilities to undertake subsequent investigation and evaluation.

This chapter provides practical guidance on issues connected with x-ray inspection rejects. It covers the immediate problems of product isolation and product handling.

17.1 Action Required if a Verification Test Fails

If, during a periodic verification test, the x-ray inspection system fails to detect or reject test samples, production should be stopped.

Product manufactured since the last successful verification test should be regarded as suspect; it should then be identified accordingly and isolated, while awaiting re-inspection.

The cause of the failure should be determined. If it's established that the failure occurred as a result of tampering or a change in production conditions, procedures should be established to prevent a re-occurrence.

If the x-ray inspection system can be adjusted to bring it back to correct operation, this should be done and the change should be noted in the test records.

If the failure is due to a system fault, then the fault should be repaired before re-starting production. In both cases, the x-ray inspection system should be re-validated before starting production.

The suspect product should be re-inspected through a known working x-ray inspection system; this system should have been set up with the same product inspection settings as the x-ray system used on the actual production line. If the reject product passes re-inspection, it can be regarded as acceptable.

17.2 Treatment of Rejected Product

X-ray inspection systems are able to reject products for various reasons, including contamination or product integrity issues. The reason for the rejection will result in different steps being required to handle the rejected product correctly.

Contamination-Only Detection

Any product rejected during a normal production run should be regarded as contaminated or defective, and it should be investigated.

The evaluation of rejected product should take place as soon as possible, in accordance with the following order of preference:

1. Immediately upon rejection or
2. Within one hour of rejection or
3. Within the same production shift or
4. Before the product batch leaves the site

Systems set up solely to inspect for contaminants will have only one reject station. All packs found in the receptacle will be contaminated products or false rejects.

An initial visual inspection of the rejected product for contamination is unlikely to be successful. However, on most x-ray machines, the reject images are stored in a library in date-and-time-stamped chronological order.

If there's only one pack in the receptacle, the most recent reject image will correspond to this pack. However, good practice is to stop the production line (if running) and run the suspect packs through the same x-ray machine on the same settings.

If this isn't possible, an off-line system should be used. If no contamination is identified, the product can be regarded as a false reject, and may be handled accordingly.

The x-ray image of each rejected pack shows the location of the suspected contaminant, offering faster location and removal of the contaminant.

After re-testing, best practice is to dispose of any product that was originally rejected by the x-ray inspection system, regardless of whether or not it's rejected at the re-test stage.

If a product's rejected at any stage during the investigation, it's essential to find the contamination – or the reason for product non-conformity, if this is occurring on a regular basis.

Other Product Defects

With x-ray systems that carry out multiple inspection routines simultaneously, a second reject station is usually installed to separate product-quality rejects from contamination rejects.

Product-quality rejects may be rejected on to a roller-track reject conveyor, for easy re-working. Visual inspection of these packs may be enough to determine the cause of rejection. If visual inspection is not satisfactory, the image library can be used – or the packs can be re-run through the x-ray system during a short production stop.

Finding and identifying contaminants or product defects in the rejected product is important because:

- If the contamination source can be identified, steps can be taken to prevent re-occurrence
- Finding contaminants can give early indication of the break-up of a piece of machinery or a problem with the production process
- If packaging and product defects can be identified, steps can be taken to prevent re-occurrence
- If line operators can see the results, it will help to build confidence in the x-ray system

17.3 Corrective and Preventive Action

Corrective and preventative actions are processes that a manufacturer must put in place to prevent contaminated or faulty products from leaving the manufacturing facility. These processes will decrease the likelihood of potential customer complaints.

Procedures should clearly define:

- Corrective and preventive actions to be taken when the presence of a contaminant is confirmed, or when a defective product is identified
- Who's responsible for determining the significance of the rejection event
- Who has the authority to hold product and assign disposal

If contamination is confirmed, there should be an immediate risk analysis to determine the significance and potential for further product contamination.

Any contamination or non-conformity should be shown to line personnel to increase their confidence in the x-ray inspection system. The samples should then be kept for future reference.

Locating and retaining contaminants has a measurable advantage. For example, a blade or a dense rubber O-ring may have broken, with fragments falling into the product. The detected pieces can be collected and the component can be re-assembled to prove that all fragments have been recovered.

Procedures should clearly define the circumstances under which production should be shut down, based upon:

- The frequency of contaminant occurrence
- The nature and type of contaminant
- The size of the contaminant

The results of any investigation (including details of contaminants found, source of contamination and actions taken) should be fully documented for future reference and on-going analysis.

17.4 X-ray System Fault Condition

The activation of a fault during a normal production process may result in a stoppage of production. If so, the necessary corrective action should be undertaken and the system should be re-validated.

When the process flow has been stopped, all product in the process flow (including any relevant downstream systems) should be collected and re-passed through the x-ray inspection system.

This should only take place when the fault has been rectified and the system re-validated.

Notes

Total Cost of Ownership (TCO)

Investment in products, machinery and systems is an integral part of a company's operation and success, so planning their acquisition and implementing them within company operations requires careful planning.

18 Total Cost of Ownership (TCO)

Wise decision-makers know their goals and carry out the acquisition and implementation process according to carefully thought-out plans. This is a far better approach than simply relying on impulses, hunches and prior experience alone.

Knowing the Total Cost of Ownership (TCO) for an x-ray system helps companies understand the total costs of acquiring and owning the system, over and above the purchase price. Specifically, TCO assesses the total cost of ownership over the service life of the investment, as well as assessing income expectations from the investment.

In addition, when suppliers have different product offers, TCO helps purchasers to compare and evaluate such offers, so as to help them make an informed decision as to the final choice of investment. Crucially, TCO can be oriented to the individual circumstances of the industry, the company, and the products being acquired. This capability makes TCO ideal for the acquisition of product inspection equipment, especially in relation to:

- Clarifying the foundations of product inspection investment decisions
- Costs that is critical for dynamic product inspection equipment
- Savings that can be made as a result of specifying the correct x-ray inspection equipment
- Calculating the Return On Investment (ROI) time of an acquisition
- Assessing the value of supplier support

18.1 Understanding Operating Targets

Within a profit-driven corporate environment, each investment requires sound reasons for its acquisition. In the food and pharmaceutical industries, the reasons for acquiring x-ray inspection systems are that they make a major contribution to quality assurance – though their installation and associated investment don't automatically guarantee better-quality products.

A clear understanding of operating targets and requirements makes a vital contribution to understanding the above process – and, closely connected to this is the knowledge obtained through the TCO assessment, covering investment service life and planned income.

Operating goals should be clearly defined before introducing a product inspection program. Possible operating goals include:

- Compliance with national, international and/or global standards, such as the Global Food Safety Initiative (GFSI)
- 100% of the products to be inspected in future ('one hundred percent check')
- Reduction (by a given percentage) of waste rate due to over-filling or under-filling
- Reduction of false rejects (incorrectly rejected good products) by a given percentage
- Reduction of quality assurance costs by a given percentage
- Increasing on-line performance (accuracy and/or sensitivity)

Each goal can be measured with the aid of traceable data – and each goal can be presented in terms of its financial implications.

18.2 Costs of an Investment

TCO can reveal the costs of an investment over its entire life-cycle – and all expenses connected directly or indirectly with the investment should be added into the calculation.

Direct Costs

Direct costs can be described as follow-up costs that can be directly attributed to an investment, and are normally easy to determine. They can include costs for:

- Procurement
- Software updates
- Operating a machine (power, compressed air, etc.)
- Wear and tear parts
- Training
- Service contracts
- Maintenance and calibration

Indirect Costs

Unfortunately, indirect costs are more difficult to determine in practice. They can't be attributed precisely to any individual investment, and usually arise if productivity is impeded in connection with the investment. Indirect costs can, for example, include:

- Failure times due to lack of maintenance, repairs, etc. causing system downtime
- Incorrect machine settings, leading to poor performance or a halt in production
- Colleagues brought in from other departments in order to resolve the problem

18.3 The Importance of the First and Subsequent Years of TCO

Product inspection TCO calculations distinguish between the costs of the initial investment (the first year) and the costs in subsequent years. The first year after the purchase is the most cost-intensive, due to the initial purchase price, installation, required training, spare parts packages, and integration into the production line. In some cases, external consulting costs, or the disposal of old systems or devices generate additional expenses.

18.4 Costs Due to the Implementation of a Product Inspection Program

When reviewing the costs of the initial investment, it's important to consider:

- Purchase price: quotations from manufacturers who were invited to bid can provide a basis for this assessment
- Installation/commissioning (initial operation): relevant quotations indicate the external costs for support by service providers, consultants or fitters. Internal costs are determined through in-house hourly rates or charge rates. The critical figure is the total time required, commencing from the stoppage of the production line for the purpose of installation i.e. integration of the equipment solution through to resumption of production
- Validation documents: costs for validation and certification, e.g. according to the standards of the Global Food Safety Initiative (GFSI) can be supplied by the manufacturer concerned
- Costs for official verifications: a good supplier will indicate all the costs for necessary official verifications, from support through to official testing
- Training with the supplier or on-site with the system: since training is offered directly by the equipment supplier, the costs are clearly quantifiable
- Purchasing costs for spare parts: a quality supplier can make appropriate statements regarding spare parts that may be required in the first and subsequent years
- Service offerings: some suppliers offer service agreements that include inspections, maintenance visits and spare parts. It's also important to check the various offers arising for service reaction time, inclusive services, price discounts for spare parts, and remote diagnostics options (remote diagnostics/remote maintenance reduces costs as aberrations can be detected earlier). As a result, any intervention by technicians can be anticipated, so that problems can be rectified more quickly

Important items to look out for in service agreements include:

1. Does the agreement include all necessary visits and services?
2. Does the agreement include a single lump-sum payment (regardless of how much service work becomes necessary)?
3. Does the agreement also include the cost of spare parts? Does this extend to wear and tear parts?
4. Does the agreement also include all travel costs and the technicians' hourly rates?

- Integration into the production line: the expense of integration can vary according to individual circumstances, such as whether a new type of equipment is being introduced or whether existing equipment is being replaced or expanded. Equipment producers can be helpful in answering these questions, and can highlight potential for optimization
- Disposal of old equipment: on request, a supplier can dispose of old equipment for a given price

18.5 Consideration of Costs Arising over Subsequent Years

When considering the costs arising over subsequent years, it's important to consider:

- Operating costs: the cost of energy and additional materials may vary widely. The x-ray system supplier should be able to supply the corresponding technical information
- Maintenance costs: the supplier can specify maintenance intervals and expenditure. A capable supplier should be able to quote average values related to repairs
- Unplanned downtime: an overview of the past (and the calculations that were previously made) is the most helpful guide here. These costs can, in many cases, be the largest costs incurred by the user, especially when the line can't run without the inspection equipment being on-line (while also functioning in accordance with specifications)
- Guarantee/warranty extension: the supplier should be able to provide the corresponding quotations and prices
- Software/hardware updates: the supplier will provide information about frequency and costs
- Personnel costs: where time is required for the creation/set-up of new products and switching of product setups (changeover), there are major differences between various suppliers' solutions. It's useful to estimate how often a completely new product needs to be set up on a production line – or how often the product set-up has to be changed over

Normally, every supplier is convinced that their particular system is the fastest and easiest to set up. However, it's best if manufacturers show potential customers exactly which working steps are necessary; then system purchasers can decide for themselves whether the operation is time-consuming and needs a lot of personnel input, or whether it saves time and costs.

18 Total Cost of Ownership (TCO)

Please enter your values in the tables below.

Overview of the costs of a typical installation

Costs	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Costs of initial investment						
Purchase price						
Installation/commissioning						
Validation documents						
Official verification costs (if applicable)						
Training with the supplier or with the customer						
Procurement costs for spare parts packages						
Service contract						
Integration into the production line						
Disposal of old equipment						
Other						
Total						

Table 18.1

Total Cost of Ownership (TCO)

Subsequent years (generally up to 5 years)

Costs	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Operating costs						
Maintenance costs						
Unplanned downtimes						
Guarantee/warranty extension						
Official verification costs (if applicable)						
Software/hardware updates and support						
Personnel costs						
Service contract						
Mandatory schedule user performance testing costs						
Other						
Total						

Table 18.2

18.6 Compare the Cost Analysis with the Possible Savings

Whenever an investment is made, the cost is usually the main focus for management and decision-makers. But the consideration of savings, in particular, over the entire lifetime of a machine, can be decisive when investing in a new system. It's therefore worthwhile including the varying savings potentials and allowing them to influence the TCO calculation.

18.6.1 How X-ray systems Can Save You Money

Investing in capital equipment requires large amounts of research and analysis into the TCO over the lifetime of the equipment. When evaluating the overall TCO of an x-ray inspection system, it's important to take the following points into consideration:

Prevention of Product Recalls

The retrieval costs of product that's been dispatched (and the costs of dealing with customers affected by a product recall) can be enormous. However, most damaging can be the cost of brand damage and the decline in sales as a result of a product recall.

When considering purchase costs, it's worth bearing in mind that a product recall (and the costs of a damaged reputation leading to loss of consumer confidence) could easily exceed the costs of the equipment that would have prevented it.

Automatic Data Collection

An x-ray system can eliminate the labor costs of manually downloading information from the machine. Automatic collection and synchronized storage allow product statistics and data to be accessed easily, so that tailored reports can be easily compiled.

Automatic Image Saving

All images can be stored with a date and time set-up – and can then be sent to a central PC. This eliminates labor costs and allows full traceability, plus easy retrieval, when required.

Automatic Machine Events Tagging and OPC-OMAC Open Connectivity Compliance

Every event can be tagged with an event code and time of occurrence. This can be sent automatically to any software platform to allow for automatic calculation of Overall Equipment Effectiveness (OEE), reducing labor costs and providing highly-accurate data.

Image-Based Inspection

Since inspection is image-based and the machine knows the exact location of the leading edge of a pack, the reject timing is extremely accurate, offering a high level of guarantee that a defective pack will be accurately rejected.

In addition, there's no requirement to test the same sample pack three separate times with a test card placed at the front, in the middle, and at the end of the pack; this reduces labor for testing times and increases productivity.

Absorption-Based Inspection

X-ray systems can see ferrous metals, non-ferrous metals and stainless steel with equal clarity (they have similar densities), so only one test card (usually a stainless steel sphere) is required to test for all these metals, reducing labor for testing time and increasing uptime.

On-board Diagnostics

All electronics are monitored, and the system will issue a pre-warning that there could be a future potential problem. This allows planned maintenance, increases uptime and reduces potential line stops.

More Than Just Contamination Inspection

As well as detecting foreign bodies, an x-ray system can simultaneously measure the mass of a pack, check fill levels, measure head space, count components, check for missing or broken products and damaged packaging, detect agglomerates such as flavor and powder lumps, and check seal integrity.

18.6.2 Achieving Savings During Product Inspection

During the implementation of a product inspection program, savings can be achieved by:

1. Reduction of scrap – accurate and reliable product inspection equipment ensures the implementation of statutory regulations and thereby prevents expensive scrap. The financial benefit can be estimated by comparing 'before' and 'after' rates
2. Reduction of re-work – additional work that results from rejected products can be calculated from additional personnel costs
3. Reduction in the cost of working time - the supplier will be able to provide information on the time for product set-up/ change-over (refitting) and on cleaning times
4. Reduction of 'wasted' material – the costs for overfills in production can be calculated, based on the sample calculation (see table 18.6.3 below)
5. Prevention of product returns – modern product inspection programs inspect 100 percent of the products produced. Deviations that run contrary to official regulations or industry standards are detected as early as possible and are avoided. Potential savings are calculated by comparison with previous production and cost of product returns
6. Protection of the brand and customer relations – non-material values such as brand and consumer loyalty can be difficult to estimate. However, they form the basis for repeat sales and can help to attract new customers

18.6.3 Reduction of the Expense Involved in Audits

Preparation of equipment tests and audits (and their subsequent documentation) can be time-consuming and costly. Suppliers should be asked for a documentation scheme that records all relevant tests and audits, and this documentation should be kept up-to-date. In this way, manufacturers can document the proper operation and use of their equipment, both internally and for the requirements of external auditors. Typical audits include the International Featured Standard (IFS) and the British Retail Consortium (BRC).

18.7 Return on Investment Times

With its cost and savings values, the TCO model provides an excellent basis for an investment decision. In addition, it supplies the financial basis for the ROI calculation which indicates when the machine has paid for itself (usually from several weeks to several years).

Comparing the costs to the savings allows for calculation of the ROI period, which is attained as soon as there is a balance between cumulative savings and costs for the total investment. The values entered for the cost and the potential savings serve as the basis for the calculation (Table 18.3).

The tables in section 18.5 itemize crucial costs. These are set against the savings that can be achieved as a result of narrower tolerances, through which overfilling and waste are reduced. The length of time required to achieve the ROI is calculated from the relationship.

The calculation is usually undertaken using special software tools that automatically perform the calculation on the basis of the given values. A good supplier should make such a tool available.

18.8 Ask for Support from Suppliers

In the course of carrying out a TCO calculation (and considering the potential savings resulting from the investment), a wide range of data is required. This data will be relevant to the useful life of the investment, from purchasing to disposal.

Truly professional suppliers represent an important source of information for the values that will be entered into the calculation. Suppliers of machines and equipment should be willing to provide relevant information, including indications of operating and maintenance costs, as well as unplanned downtimes. Active support at the investment planning stage is therefore an important factor when looking to select a supplier.

Total Cost of Ownership (TCO)

Please enter your values in the tables below.

Overview of the possible savings

Savings	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Reduction of waste						
Reduction of rework						
Reduction of work required						
Reduction of product "giveaway"						
Avoidance of returns						
Protection of brand reputation and customer relationship						
Reduction of expense involved in audits						
Reduction in lost downtime						
Reduction in the costs of mandatory testing						
Other						
Total						

Table 18.3

How to Prove Due Diligence

Food manufacturers must take every precaution to ensure that their products are safe, that they are free from contamination and that they are unlikely to harm the end consumer in any way.

Manufacturers should therefore take steps to ensure that systems and procedures are in place to minimize the risk of litigation. They should also possess the necessary documentary evidence to prove they have been diligent in carrying out the proper manufacturing process.

19 How to Prove Due Diligence

19.1 Due Diligence in the Context of Standards

This chapter explains the need for due diligence and describes how an x-ray inspection system can provide the necessary components for a due diligence defense.

19.1.1 Duty of Care

In law, individuals have a 'duty of care' which requires that they adhere to a standard of reasonable care while performing any acts that could, foreseeably, harm others.

The 'standard of care' is the degree of watchfulness, attentiveness, prudence and caution of an individual who has a duty of care.

In the food industry, the standard of care is determined by the care that would be taken by a reasonably prudent manufacturer of a given product.

Failure to meet the standard could be regarded as negligence, and any resulting damages could be claimed in a law suit by an injured party.

19.1.2 Due Diligence: What is it?

The due diligence defense is available to manufacturers accused of a breach of food safety regulations. Essentially, the defense is that the accused person took all reasonable practicable steps to avoid the breach. It's a sufficient defense for the person charged to prove that:

- All reasonable precautions were taken.
- They exercised all due diligence to avoid the occurrence, whether personally or through any person under their control.

'Taking all reasonable precautions' includes setting up systems of control which are appropriate to the risk. What's 'reasonable' is determined by the size and resources of the business.

'Exercising all due diligence' involves having procedures in place which review and audit the system to ensure it operates effectively.

Whether or not a defense of due diligence will be successful depends on the circumstances surrounding each case.

19.1.3 Hazard Analysis and Critical Control Points

In food production, most manufacturers utilize a system based on Hazard Analysis and Critical Control Points (HACCP). This acts as a framework for identifying where hazards might occur.

The HACCP structure is used to put procedures in place to minimize the chance of the hazard occurring in the first place. The HACCP process strictly monitors and controls each manufacturing step to reduce the probability of hazards occurring.

As previously discussed (see Introduction) HACCP is based on seven core principles.

19.1.4 Standards

For many years, the food industry had many different auditing standards. These were chosen in accordance with:

- The preferences of manufacturers' most significant customers.
- The particular choices of individual plants.
- Strategic selection by companies. This was so that they could achieve tactical levels of quality control by utilizing a particular set of standards.

As a result of this lack of common standards, the industry was vulnerable to inconsistent protection, which put consumer safety and businesses at risk.

To solve this problem, the Global Food Safety Initiative (GFSI) was established by a group of world retailers in May 2000. The GFSI now reviews food safety standards and approves those which meet specific criteria.

Different standards apply to different stages in the food supply chain, and many food manufacturers now only need to certify themselves in accordance with one of four standards, in order to meet most retailers' requirements; however, some larger retailers also have their own standards.

HACCP and Pre-Requisite Programs (PRP) define good practice in hygiene and manufacturing – and are the foundation of all GFSI standards.

From 1 January 2006, EU food hygiene legislation has applied throughout the UK, and food business operators (except farmers and growers) are now required to put in place, implement and maintain a permanent procedure (or procedures), based on HACCP principles.

The GFSI now represents an association of companies, and issues thousands of food safety certificates annually under one of the following four HACCP GFSI-approved standards:

1. The British Retail Consortium – BRC v7
2. The International Featured Standard – IFS v6
3. FSSC22000
4. SQF

Other schemes exist, but the four listed above represent over 90% of the adopted standards currently being implemented in the food industry.

Some food retailers adopt a different approach; investing heavily in the GFSI, they have established their own Codes of Practice which are designed to support the GFSI-approved HACCP-based standards.

In addition to the standards, both SQF and the BRC publish guidance documents. The BRC also includes a 'Contamination Control' guidance document relevant to inspection equipment.

These documents contain information on how the standards should be interpreted. Whereas the standards are written using the words "shall" or "must", the guidance documents are written using the word "should".

These guidance documents present a state-of-the-art interpretation of how to implement the standards and many auditors and certification bodies expect food manufacturers to implement standards in accordance with them. The standards are, increasingly, being accepted across all continents – and, while they are not a legal obligation, almost all retailers now insist that manufacturers are certified to one of them.

19.2 X-ray Inspection System: Concerns and Solutions

There are many ways that contaminants can find their way into a food product. The majority of equipment used in food processing plants is made of metal. Cutting blades, grinders, mixers, transport conveyors and packaging machinery are all predominantly metal-based; mineral stones, glass shards are also commonly collected during the harvesting of foods.

It's quite possible that some of these items could find their way into the manufacturing process during normal working processes. However, an x-ray system downstream of all processes should ensure that the resulting food product has been checked for the inclusion of contaminants.

X-ray systems are a common sight in most modern food manufacturing plants, and the technology employed is considered to be highly reliable.

However, simply installing an x-ray system will not guarantee contaminants will not reach the end user. A comprehensive approach to Quality Management must also be employed and, as many x-ray systems are defined as Critical Control Points (CCPs), each CCP should be managed accordingly.

An x-ray system fitted with a suitable reject mechanism and lockable reject bin will make a major contribution to providing an effective solution to ensuring contaminant-free product; however, a system or procedural failure can have a serious impact on the overall effectiveness of the system employed.

How to Prove Due Diligence

It's vital to ensure that all contaminated food packages are rejected efficiently from the process or packing line, and that they remain rejected. It's equally important to provide the highest levels of compliance with the relevant standards. To help achieve these aims, the table below identifies various concerns or problems, together with matching solutions designed to tackle each problem.

Concern	Solution
How can I ensure that contaminated product is detected in accordance with the highest levels of performance and efficiency?	Install an x-ray system capable of detecting all contaminant types; understand its ability to detect the range of contaminants such as metal, glass, mineral stone and calcified bone.
X-ray system failure leads to costly downtime. How do I maximize uptime?	Undertake a preventative maintenance program on the x-ray system (see Chapter 12).
How do I ensure that the x-ray system is set correctly? And how can I ensure that I don't suffer from false rejections?	Ensure that the x-ray system has an accurate auto set-up feature and has been set up by trained operators.
If contamination is detected, how can the contaminated pack be rejected from the process without causing production stoppages?	Utilize an automatic pack reject mechanism that's been designed specifically for the application in question, preferably with a reject verification feature.
How can I ensure that consecutive contaminated packs are rejected? And how do I guarantee that the correct pack is rejected, irrespective of the position of the contamination within the pack?	Ensure that the reject mechanism works in conjunction with the imaging of the pack which controls the operation of the reject mechanism. An encoder can also be used for variable line speeds.
How do I ensure that I have a sufficient supply of compressed air to deal with multiple reject events?	Fit an air reservoir to the system or fit an air failure switch to the conveyor's pneumatic feed.
How do I ensure that the reject mechanism is functioning correctly when the conveyor system runs from a variable-speed drive?	The timing of the reject mechanism must be controlled via a belt speed encoder. This will ensure accurate rejection, irrespective of belt speed.
How can I ensure that contaminated product is not taken from the line in the period between detection and rejection?	This is not possible on an x-ray system as it's in a continuous guarded tunnel.
Where should the contaminated packs be collected when they are rejected?	Inside a reject collection bin that's securely lockable with a key or electronic lock.
How can I ensure that the contaminated pack has been rejected from the process or packing line?	Install a reject confirmation system.
What if the reject bin fills up with contaminated product and there's no more room to accommodate further rejected product?	Install a 'bin full' sensor at the 80% full level. Set the sensor to trigger an alarm if the situation becomes critical.
How do I prevent unauthorized removal of rejected products from the reject collection bin?	Manage the key accordingly or install a 'bin door locked/unlocked' alarm. Ensure that only authorized password holders have access rights.
How can I confirm the reject confirmation system is working correctly?	Fit a reject confirmation challenge key switch for periodic testing of this feature.
How can I be alerted if a problem occurs?	Install a warning beacon stack with an audible or visual alarm linked to a conveyor 'stop' function.
How can I be sure that operators don't override the system when a problem occurs?	Use a key-protected conveyor override, or set the software option to require a high-level login.
How can I demonstrate increased levels of user compliance with standards? How can I set up an audit trail?	• Utilize an x-ray system with individual language-specific high-security operator access levels and. • Utilize a built-in log with time and date stamp to record all access to x-ray system controls. • Document procedures throughout all processes, and keep detailed records of all operator training. • Subscribe to an external annual audit and certification process.

Table 19.1

Fig 19.1

19.3 Components of a Failsafe X-ray System

The individual components of a failsafe x-ray system will now be considered in detail.

19.3.1 X-ray System

An x-ray system should meet required detection standards, so it must be capable of being set up to operate within the sensitivity guidelines described in either the food manufacturer's code of practice – or in line with the requirements of third party customers, such as retailers.

When comparing the sensitivities of one x-ray system with the sensitivities of another, the purchaser should ensure that the same test sample types are used to avoid unfair comparisons, e.g. there are several different types of glass test piece in use amongst different suppliers.

19.3.2 Automatic Pack Reject Mechanism

Where possible, the system should include an automatic product reject mechanism, which is activated when the x-ray system identifies contamination.

Its purpose is to remove the contaminated pack(s) from the production line before they are dispatched. The type of rejection mechanism should be selected specifically for the products that are being inspected. It should take into account:

- Line and pack speed.
- Pack weight.
- Pack shape.
- Dimensions.
- The nature of the packaging material.

Taking into account these factors ensures maximum rejection capability, and removes reliance on line operators – which can often be the major cause of system failure. It's recommended that only in extreme circumstances should the use of a 'stop-alarm and 'manual rejection'-type system be specified.

Many types of reject mechanisms are available. Most are pneumatically-operated, such as air-blast mechanisms, pushers, and sweep arms. Such pneumatically-operated reject systems may be fitted with an air failure switch, which will raise an alarm if the air pressure falls below a critical point that could prevent efficient rejection.

To increase the overall failsafe nature of pneumatically-operated reject systems, air reservoirs can also be fitted.

Automatic reject systems are discussed in depth in Section 4.4 of this Guide.

19.3.3 Pack Sensor and Conveyor Speed Encoder

If using a conveyor system that utilizes a variable-speed drive, a belt speed encoder should be used in conjunction with the x-ray inspection system to control the operation of the reject mechanism.

This ensures that the time between detection and the reject mechanism operating is calculated accurately, enabling the reject mechanism to identify the contaminated pack, whatever the line speed. This is also a requirement if the line is prone to frequent stopping and starting.

19.3.4 Lockable Reject Collection Bin, Reject Confirmation Sensor, and Bin Full Sensor

The reject collection bin provides temporary storage for rejected (i.e. contaminated) packs. The bin must be lockable, to make sure that contaminated packs can't be removed and re-introduced into the production line after inspection.

The key for the lock should never be left in situ, and it should be held by a senior/authorized staff member. This removes the opportunity for others to gain access to contaminated product – a process which is consistent with due diligence and HACCP principles.

A reject confirmation sensor should be situated in (or across) the mouth of the reject bin. Once a contaminant has been detected, the system can be configured to expect a further signal from the reject confirmation sensor that a pack has entered the reject bin.

If no such signal is received, a system alarm is raised and the conveyor is stopped. The reject confirmation system must be intelligent enough to handle multiple detection events.

A 'bin full' sensor removes the risk that a contaminated pack might not be removed from the conveyor because the reject bin is full of rejected product. Once the level in the bin approaches its capacity (recommended to be set at 80% full), an alarm can be activated.

Alternatively, the conveyor can be configured to stop so that the bin can be opened and the reject packs can be removed for disposal. This avoids the risk of a failed rejection due to the reject bin being full.

The x-ray system can be configured to activate a timer when the reject bin door is opened, and can automatically shut down the system if the bin is accidentally left open for more than a pre-set time.

Likewise, specially-designed systems can eliminate the need for a physical key by providing an unlocking password. This further improves the security and integrity of the reject bin, since only authorized personnel can gain access.

19.3.5 Key-operated Switch Re-set

There are several failsafe elements that result in the conveyor being stopped and the x-ray system can be configured to request high-level access to re-set.

Only authorized personnel should be allowed to re-start the system after the fault or condition has been rectified.

19.3.6 Warning Beacon Stack

A warning beacon stack attached to the x-ray system can signal warning faults. It's usually a high-visibility color-coded fault beacon, enabling rapid identification and rectification of the problem. This will help to ensure that downtime is kept to a minimum.

Audible alarms can also be configured to activate when the warning beacon operates. It's recommended that if any of these fault conditions occur during normal manufacturing, the process should cease immediately until the fault condition is rectified and the system has been validated and documented as fully-functioning by the appropriate system test procedure.

19.3.7 Access Log and High-Security Log-in Facility

Sophisticated x-ray systems can assist the user in complying with standards, and can also provide an audit trail. This process can be achieved by issuing unique single-user passcodes, and by making these passcodes language-specific. This ensures each user carries a level of personal responsibility for his/her actions.

A system of this type is normally sufficient to prevent misuse, and provides a foundation for regular inspections. Such inspections provide the basis of a due diligence defense.

In such systems, an automatic log is produced. This records all log-ins made at the x-ray system, as well as the date, time and name of the person logging on.

By recording this information and instituting system access only through individual password control, compliance with standards and HACCP record-keeping requirements can be demonstrated. These form a robust basis for a due diligence defense.

19.4 Management Responsibility

As many x-ray systems in use are now considered to be CCPs, it's a management responsibility to ensure that all personnel treat these control points accordingly.

Operators must be aware that their actions are critical to the operation of the control point, and that any misdemeanor will be subject to disciplinary action.

19.5 Checklist

When considering the purchase of an x-ray system to meet due diligence needs, this chapter can be used as a checklist to evaluate alternative systems. If a proposed system doesn't include some (or all) of the features identified, it's likely to indicate a weakness in its ability to mount a full due diligence defense.

19.6 References

Food Standards Agency (FSA)

http://www.food.gov.uk/

International Featured Standard (IFS)

http://www.food-care.info

Safe Quality Food (SQF) Institute

http://www.SQFI.com

British Retail Consortium (BRC)

http://www.brcglobalstandards.com/Manufacturers/Food.aspx

FSSC22000

http://www.fssc22000.com/documents/home.xml?lang=en

Data Analysis and Program Improvement

The long-term effectiveness of an x-ray inspection program can only be determined by efficient data collection and thorough trend analysis. A properly-managed x-ray inspection system should be able to help eliminate the causes of contamination and other product faults, so the collection of data is the first step in measuring the system's economic value in terms of cost-savings and increased profit.

This chapter examines the data sources that can be analyzed to assess the operational effectiveness of an x-ray inspection program. It also highlights some of the potential rewards of data analysis in terms of system improvement.

20.1 Data Analysis

Data can be collated, analyzed and used in many different ways. The most effective method of data collection and examination will vary from organization to organization, and will be dependent on the needs and capabilities of the individual business.

It's vitally important that the source data is accurate and reliable, and that the conclusions drawn from its analysis are clear. This will help to secure support for those conclusions (and the actions that follow) throughout the organization.

Once the data has been analyzed, the conclusions and recommended actions need to be communicated to those who originally provided the source data. This will help to ensure that data flow is sustained over time. If staff see that data is not being used to good effect, its value will be questioned, resulting in reduced discipline in data collection and recording.

Wherever possible, a cost element should be included in the process of gathering and analyzing data. This will help to ensure that resulting improvement initiatives are properly prioritized in order of importance; in turn, this will provide sufficient justification for the additional capital expenditure required to ensure that improvements are made.

20.2 Program Improvement

The following are just a few examples of the types of analysis that can prove beneficial when reviewing and improving x-ray inspection programs. The same principles can be applied to a variety of data sources.

20.2.1 Customer Complaints

Every contamination-related or product integrity-related customer complaint should be investigated to determine the cause of complaint. Program documentation and records will greatly assist in the investigation – and such information may even prove useful as evidence when defending an unjustified complaint.

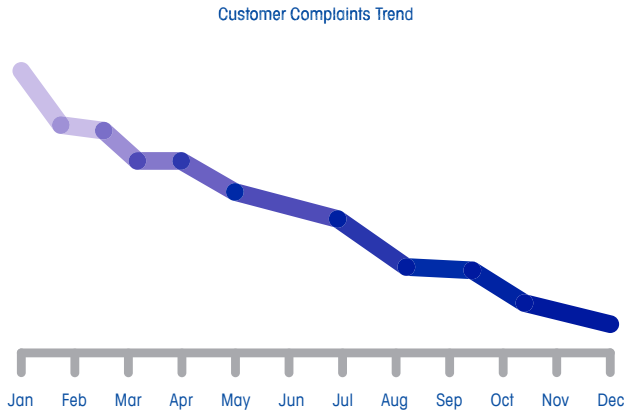

Figure 20.1

The investigation should seek to:

- Determine the cause of the fault.
- Identify any ineffective monitoring of the Critical Control Point (CCP).
- Highlight any new unidentified CCP.
- Establish whether the detected contaminant is smaller than the operating sensitivity performance of the x-ray inspection system.

Corrective and preventive action should be taken as appropriate, and the x-ray inspection program should then be improved to eliminate any faults.

The number of complaints and assigned causes should be monitored over time, to make sure that improvements are being made (Figure 20.1). As a result, underlying common causes can be identified and eliminated. This process can drive -improvements in the reduction of complaints, with the eventual aim of reducing them to zero.

20.2.2 Food Safety and Management System Audits

Usually conducted by an organization's internal quality department (or by external regulatory bodies and customers), these audits offer an independent review of the x-ray inspection program's effectiveness.

Feedback is a valuable source of information, especially when received in the form of an official 'non-conformance' – in other words, non-fulfillment of specified requirements required by an official process such as an audit.

Feedback can also provide an opportunity for improvement – and ongoing analysis of audit findings can give additional assurance of effective operation; alternatively, that analysis of audit findings can identify system weaknesses that need to be improved.

20.2.3 Detection Events

Detection events are caused by actual contamination of glass, metal, mineral stone, calcified bone or high-density plastic. Detection can also be caused by deviations from approved standards of manufacture.

In some instances, false rejects may occur – but modern x-ray systems include technology to help minimize false reject rates. Detection event information should be collated regularly and monitored on a trend chart to identify common causes of contamination.

Analysis of contamination type and frequency of events can be conducted line-by-line or machine-by-machine. This process can identify particular sources of concern, such as the quality of raw material ingredients provided by individual suppliers. Other sources of concern may, for example, be inefficient production staff training methods or inadequate maintenance routines.

There should be a clear distinction between normal production-reject events and those reject events which occur when carrying out routine verification tests. Good x-ray systems will be able to separate these two sets of statistics. (see Section 16.4).

Analysis of false rejects helps to identify poor installations; it also assists in identifying equipment that's become unreliable or systems that can no longer cope with the required limits of detection. Such data could therefore be used as justification to upgrade to a more modern and capable x-ray inspection system, or it could provide evidence for the need to re-train operators on existing machines.

20.2.4 X-ray Image Library

Advanced x-ray systems store images of all rejected packs, and these images are date-and-time stamped with the product name. The images can be taken off the x-ray machine and stored on a manufacturer's computer in chronological order (see Chapter 21). In this format, they offer excellent traceability for any customer complaints/returns. This is because the production times/codes can be immediately cross-referenced.

20.2.5 Verification Tests

The results of verification tests should be monitored and analyzed on an ongoing basis. If tests are conducted frequently (e.g. every 30 minutes), and analysis over time shows that the tests are always positive, consideration should be given to reducing the frequency of testing. This should take into account factors such as failsafe system design, access control and probability of detection.

Caution should always be exercised to ensure that any external standards or codes of practice in place are not contravened and that the risks involved are known and acceptable.

20.2.6 Maintenance Records

When analyzing preventive maintenance records and incident reports, the results may show that a particular piece of equipment rarely needs maintenance. If so, there may be justification for reducing the frequency of maintenance, providing this doesn't contravene the equipment provider's recommendations or risk assessments.

Alternatively, data analysis may indicate that maintenance is required more often and that test frequency should be increased.

20.2.7 General

There are many other sources of data that can be analyzed to good effect, and it's important to focus on areas that generate the greatest return in terms of increased profitability and reduced risk.

Ongoing analysis of program data can identify underlying common causes that, in isolation, don't appear significant. However, when considered in terms of their frequency of occurrence, these common causes can create the incentive to prevent their occurrence in the future.

Notes

Connectivity Solutions

In today's highly-accountable business world, considerable value is attached to real-time production data from process machinery and operators at shop-floor level. With enterprise-wide management systems, this type of data is widely available across remote departments and multiple production sites – so anyone involved in the day-to-day running of an organization is just a computer keystroke away from mission-critical information.

21.1 Understanding the Importance of Connectivity

There are many benefits to the process of installing factory management systems and then integrating x-ray inspection equipment into them. For example, a well-designed system can include facilities for:

- Remote Monitoring
  - Monitoring of process events such as reject images, performance tests and pack counts
  - Monitoring of running conditions, faults and warnings
  - Communication of alerts and warnings
- Remote Management
  - Changing of product inspection settings
- Remote Servicing and Back-up
  - Online diagnostics, see Section 5.11
- Data collection and recording
  - Recording of performance data, test routines and x-ray images
  - Providing data for product traceability
  - Providing proof of risk management and compliance with industry regulations

21.2 Connectivity Media

Data from x-ray inspection systems can normally be retrieved straight from an external USB port or exchanged via an Ethernet port. Both connections should have IP65 closures as a minimum requirement.

21.2.1 ProdX

ProdX is a complete stand-alone networking package for all Mettler-Toledo Product Inspection devices. ProdX is used for producing a wide range of reports based on stored historical data. It also shows real-time data (individually for each device connected). In addition, ProdX archives reject images for later viewing, and allow customers to implement product changeovers remotely. ProdX is PackML compliant and the stored data can assist with calculating Overall Equipment Effectiveness (OEE).

21.2.2 Web Server

X-ray systems could expose images and reports by hosting an internal Web Server. Users can then access this data using a web browser on their LAN.

21.2.3 Ethernet/IP (Industrial Protocol) Communications

Modern manufacturing facilities frequently incorporate Ethernet/IP networks for the transfer and exchange of process and manufacturing data. This enables x-ray inspection data to be viewed on networked PCs or other devices (Figure 21.1). This data can be accessed using a number of different technologies including via a web server, a standard field bus protocol (OPC, Ethernet/IP, etc.) or via the manufacturers proprietary comms protocols.

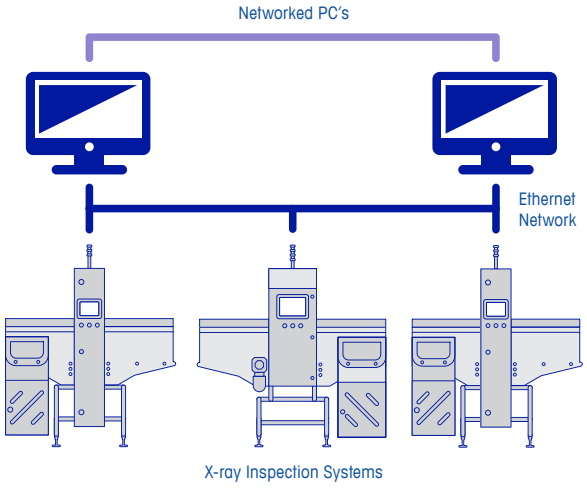

Figure 21.1

21.2.4 Virtual Networking Computing (VNC)

VNC allows users to view exactly what's being seen on the x-ray screen; users may be viewing from a remote location but the effect is as if they are standing directly in front of the x-ray system screen.

VNC software is run on a computer which is plugged into the x-ray inspection system, either directly or via a network using the machine's IP address. As well as providing an x-ray screen view, the computer also enables customers to control the x-ray system remotely. VNC is not able to export data for any report generation.

21.3 Web Server

A web server is the simplest form of connectivity. On an x-ray system, it provides a snapshot of real-time inspection information to a PC on the same Local Area Network (LAN). The connection is very simple to set up, and is made via the IP address. It allows for multiple machines to be connected.

21.4 Manufacturer's Proprietary Comms Protocol

Some manufacturers supply a proprietary communications protocol to facilitate communications between x-ray systems and PCs. Real-time data is exported from the x-ray system, but manufacturers need to provide a front-end software solution to manage the data.

21.5 Open Platform Communications (OPC) Technology

In most manufacturing plants, people generally like to gather and view data from multiple processes and applications on the same computer screen or interface. However, this can be problematic, since the various pieces of process equipment are likely to communicate using different languages.

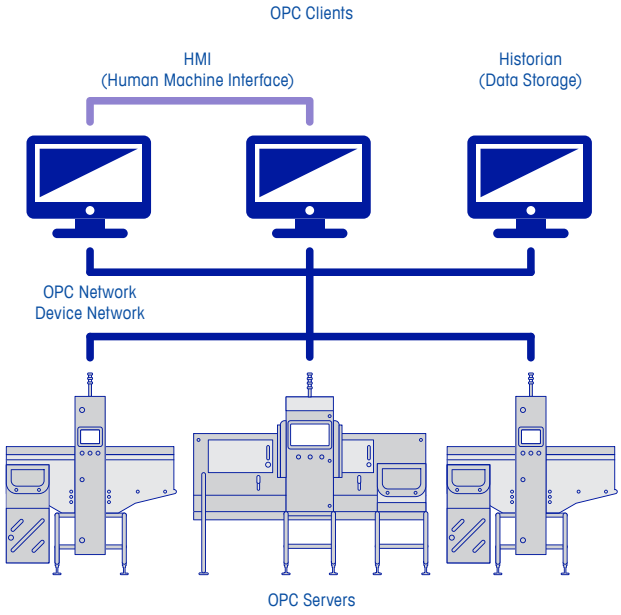

Figure 21.2

OPC technology addresses this problem by allowing the controller to 'talk' to all machines using one common language. The data gathered on the OPC server can then be presented in a user-friendly format on a single-user interface PC.

Alternatively, information can be accessed from a network of business-wide PCs, using standard factory-management client system software (Figure 21.2). Now recognized as a global standard, OPC provides seamless communications for all manufacturing installations.

Key benefits of OPC technology include:

- Simplified communications system design.
- Real-time monitoring and control of data, e.g. reject images, batch and shift production data.
- Standard technology used across multiple production processes, facilitating full integration.
- Reduced dependency on multi-vendor solutions.
- Being OMAC-compliant, OPC data can automatically calculate Overall Equipment Effectiveness (OEE) in order to monitor production-line efficiency.
- Compatibility with Supervisory Control And Data Acquisition (SCADA) systems.

21.6 SCADA Systems

SCADA factory-management systems are becoming commonplace in many manufacturing environments. These highly-customizable, sophisticated systems can be used to provide data from multiple processes at a single interface, either by direct communication with individual pieces of process equipment, or via communication utilizing OPC server technology.

21.7 Ethernet Industrial Protocol (Ethernet/IP)

An x-ray system should have Ethernet/IP capability that implements the Common Industrial Protocol (CIP). CIP encompasses a comprehensive suite of messages and services for a variety of manufacturing automation applications, including control, safety, synchronization, motion, configuration and information. Ethernet/IP allows direct communication with modern industrial PLC systems.

Notes

Notes

Product Inspection Solutions

Protection

Productivity

Quality

www.mt.com/safeline-xray

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