White Paper

Radiation Safety: How to Ensure Full Regulatory Compliance

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Radiation Safety: How to Ensure Full Regulatory Compliance

Since the use of x-ray equipment for product inspection began around the early 1900s, it has become increasingly popular globally as food manufacturers strive to protect consumer welfare, safeguard their brand reputations, and comply with stringent food safety regulations and industry standards.

In addition to detecting physical contaminants, including metal, glass, mineral stone, calcified bone, and high-density plastics and rubber, x-ray systems are simultaneously capable of measuring mass, counting components, monitoring fill levels and inspecting seal integrity.

As x-ray equipment generates ionizing radiation, its use is highly regulated and it is the owner's responsibility to ensure equipment operates at safe levels of radiation.

This white paper explains what ionizing radiation is and puts radiation doses into context, before looking at how safety regulations differ between countries and states. The paper goes on to explain that modern x-ray systems are built to protect users from the effects of radiation, and how x-ray equipment suppliers can support companies with radiation safety and regulatory compliance.

1. Ionizing Radiation

X-rays are a form of electromagnetic radiation and are invisible, like light or radio waves. All types of electromagnetic radiation are part of a single continuum known as the electromagnetic spectrum. The spectrum runs from long-wave radio at one end to gamma rays at the other. X-rays used for food inspection should not be associated with radioactive materials, such as uranium. Radioactive materials are physical sources of radiation which emit radiation continuously and cannot be switched off.

X-rays used for food inspection can be switched on and off, like light from a bulb. When the electricity supply to the x-ray system is switched off, the flow of x-rays ceases instantaneously.

Ionizing radiation is radiation with enough energy to remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionized. Only the high frequency portion of the electromagnetic spectrum is ionizing which includes x-rays and gamma rays.

2. Putting Radiation Doses into Context

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 Ralf Maximilian Sievert, a medical physicist who studied the biological effects of radiation. As occupational radiation 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).

Each member of the world population is exposed to approximately 2,400 µSv of ionizing radiation every year from natural sources[1]. This far exceeds the radiation exposure received from a properly-installed and maintained x-ray inspection system. For Europe, the public level of ionizing radiation an individual can obtain from exposure to an industrial machine, for example, is only is 1mvSv/a.

Eating one average 150-gram banana daily for a year, for example, exposes an individual to 36.5 µSv a year of ionizing radiation. Furthermore, frequent fliers absorb around 8% more radiation (200 µSv a year), compared to non-fliers. The frequent flyer's typical annual dose is approximately 2,600 µSv a year. Pilots and cabin crew absorb more still, about 4,400 µSv, depending on routes flown and total flying time. Their annual dose of radiation is typically greater than workers at a nuclear plant, and almost twice as high as those who spend their lives at ground level[2].

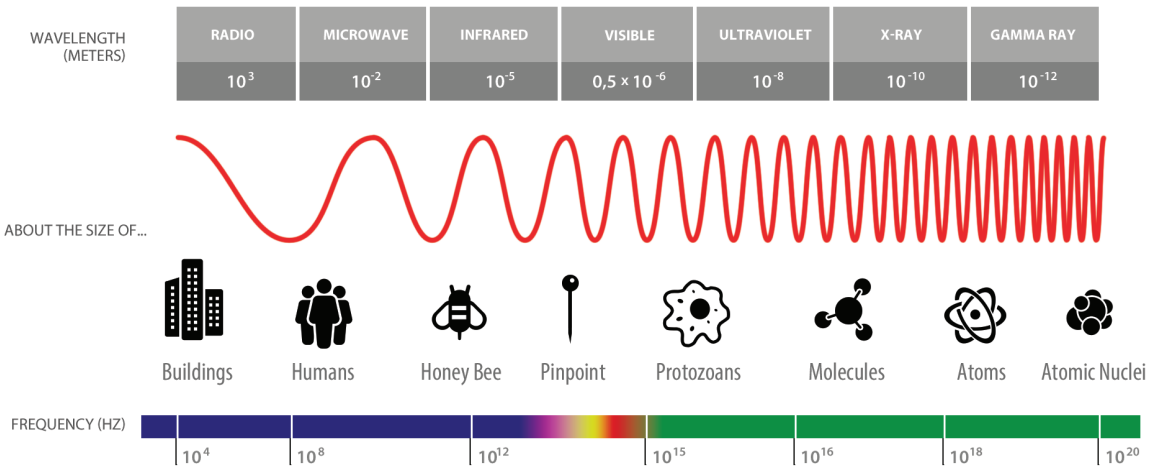

Figure 1: Electromagnetic Spectrum

3. Safety Regulations

Food x-ray inspection equipment is regulated to ensure it is safe to use, even if an operator has to stand next to the machine for every hour of the working day. In practice, operators spend very little time close to x-ray equipment as modern systems are automated to minimize operator involvement. Nevertheless, x-ray systems must comply with local rules and regulations on the use of ionizing radiation.

Such regulations vary from country to country and from state to state. Europe overall is stricter than the United States or Canada with regard to radiation emission limits. US regulations specify, for example, that the maximum allowable radiation leakage levels should not exceed 5 µSv/hour at 5 cm from the x-ray system.

After analysis of the Ionizing Radiations Regulations 1999 and Euratom, the European industry decided that radiation measurements taken from the machine should be based on the assumption of a yearly dose of an individual working on a machine at a standard amount of time (8 hours a day, 40 hours a week, 52 weeks a year). In the case of x-ray systems, it is considerably less as machines can run automatically - they can be manned 25% of the time and calculated as 50% which is considered a worst case. Once calculated, the final figure of 0.5µSv/hour is totaled if the machine is manned full time using worst case values, or alternatively 1 µSv/hour if manned 50% of the time. There is some variation as to what distance the measurement should be made from the surface plane of the machine, however it has been agreed upon that the distance should be less than 10 centimeters.

In most cases, the rest of the world follows EU standards. However, some countries' regulations do not contain anything specific to cabinet x-ray systems, they simply generalize with radiation itself.

Companies usually have within 30 days to fill out the appropriate registration form. However, some countries do not have official forms. In which case, companies are required to provide a compliance letter, containing the x-ray system's serial number. X-ray system manufacturers will also self-certify equipment to state that it has been manufactured to comply with a country's regulations as they pertain to cabinet x-ray.

Eventually an inspector will come out to inspect new x-ray equipment. Some regulators send a registration certificate and others will send a number or bill. There is usually a small fee attached.

Some US states require registration prior to operation, including Delaware, Hawaii, Idaho, Kentucky, Maryland, Massachusetts, Mississippi, Ohio, South Carolina, West Virginia, and Wisconsin. It is important that x-ray inspection equipment is regularly tested and certified to meet these safety standards.

Service technicians in the US can verify compliance using a radiation detection instrument which has been calibrated to a NIFT (National Institute of Standards and Technology) traceable source in the US. Other agencies exist in Europe.

Country	Regulatory Standard
Australia	RHS (Radiation Health Series) 21
Canada	RED (Radiation Emitting Devices) Act Ontario - Pre-Start Health and Safety Reviews
China	GB18871-2002
France	NFC-74-100 NFC-15-160
Spain	UNE 73-302
United Kingdom	Ionizing Radiations Regulations 1999 (IRR 2017 due out Fall 2017)
United States	CFR 21 Part 1020.40 (cabinet x-rays)

Figure 2 : Examples of key regulations by country.

4. Registration of New X-ray Equipment

New x-ray inspection equipment must be registered with the country or state's Radiation Control Agency. This involves notifying the Agency of the installation location and date. In the UK, companies must notify the HSE of their intention to work with radiation in accordance with regulation 6 of the IRR 1999. Registration requirements and registration fees vary from state to state in the US. Applicable state Radiation Control Agencies can be found on the following website www.crcpd.org. Companies should contact their state Radiation Control Agency to obtain a current copy of the Application for a Radiation Generating Machine and ask about the fee for a cabinet x-ray system.

In the US, an x-ray system's placement must also be registered with the Food and Drug Administration (FDA). X-ray systems that are located in a single building or in a group of buildings that are contiguous to one another, and used by the same operator, can be treated as a single radiation installation.

5. Installation Compliance

When using x-rays for product inspection, the x-ray system must be installed to comply with local rules, as well as regulations on the use of ionizing radiation for the country in which the machine is being used.

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 is recommended that installation is only carried out by a qualified service engineer. Once installed, all x-ray systems are subject to a final critical radiation survey to prevent accidental exposure. If they pass, a certificate is issued. This survey should be undertaken by the Radiation Safety Officer (RSO)/Radiation Protection Supervisor (RPS) who will act as the point of contact for any x-ray safety questions. More information about the role of the RSO/RPS can be found in section 7.

Some countries and US states require a radiation leakage survey to be performed annually, while others require it to be performed biannually or even quarterly.

X-ray system manufacturers are required to provide the purchaser with manuals and instructions which provide both technical and safety information. Before operation, it is important that all staff are trained in the proper use of the x-ray equipment and in the relevant health and safety issues.

6. Standards for Protection Against Radiation

In the US, the Nuclear Regulatory Commission (NRC) oversees the use of radioactive materials and sources of radiation and establishes the "Standards for Protection Against Radiation" 10 CFR 20.

A total of 39 states have entered into a contractual agreement with the NRC to oversee the use of radioactive materials and sources of radiation within their state boundaries.

Figure 3 : Map of states in contratctual agreement with NRC to oversee use of radioactive materials.

Most of the Standards for Protection Against Radiation regulations are not applicable as cabinet x-ray systems do not contain any radioactive material.

7. Radiation Safety Officer (RSO)

In the US, the RSO is the person within an organization responsible for the safe use of radiation and radioactive materials, as well as regulatory compliance. An organization licensed by the Nuclear Regulatory Commission to use radioactive materials must designate an RSO in writing.

A Radiation Protection Supervisor (RPS) is appointed for the purpose of securing compliance with the Ionizing Radiations Regulations 1999 in respect of work carried out in an area which is subject to local rules.

- Develop and implement the written radiation protection program and review this program annually.
- Post the "Notice to Employees" in several areas where employees may view.
- Provide instructions concerning hazards and safety practices to individuals who work with or may be exposed to radiation from the x-ray unit (Instructions to Worker).
- Determine "Prior Occupational Dose" of all individuals monitored for occupational dose.
- Maintain records of formal training instructions, test results, calibrations, radiation surveys, performance tests, inspection logs and equipment maintenance records.
- Check the x-ray system for defects and verify equipment parts are maintained according to manufacturer's specifications each day, and document the results.
- Test and inspect the x-ray system quarterly for proper functioning of warning devices, control devices, and components important to safety, and document the results.
- Perform and document, or have performed, a radiation safety survey (radiation leakage survey) of the x-ray system initially upon installation, anytime the system is relocated or when changes occur that could affect radiation levels (i.e. shielding changes) and at a minimum, intervals not to exceed one year (annual radiation leakage survey). Some States require a survey quarterly, while others such as Georgia, Idaho, Ohio and Nebraska require it biannually.
- Perform a radiation survey of the Restricted Area and the Unrestricted Area after surveying the x-ray system, as well as perform a quarterly x-ray unit inspection and interlock safety test.

Figure 4 : Eagle™ Pack 240 XE x-ray inspection machine with stainless steel cabinet and highly-visible lamp stack.

8. Safety Design Features

Modern x-ray inspection systems used in the food industry do not contain any sources of live radiation, such as uranium, and are designed to protect users from the effects of radiation.

X-rays are electrically generated which means they can be turned on and off, plus the x-ray generator is encased in a stainless steel x-ray cabinet with a highly-visible lamp stack that signals the system status. The lamp stack is wired to a safety circuit; if the lamps fail, the x-ray source automatically switches off. The cabinet itself is very safe, but as a general rule before opening any access louvers to the cabinet, the x-rays should always be switched off.

In addition, all access to primary x-ray beam radiation is protected by two forced break interlocks and monitored by a safety relay. Furthermore, the radiation dose levels used for food inspection are extremely low.

In accordance with FDA regulations Title 21 CFR Part 1020 – "Performance Standards for Ionizing Radiation Emitting Products", each cabinet x-ray system shall be tested and certified to meet the applicable performance quality standards of 21 CFR 1020.40, "Cabinet X-rays":

- The insertion of any part of the human body through any port or aperture into the primary beam shall not be possible.
- Each access panel shall have at least one safety interlock.
- A key actuated control is required to ensure that x-ray generation is not possible with the key removed.
- A control or controls to initiate and terminate the generation of x-rays other than a safety interlock or the main control panel (e.g. emergency stop) is required.
- For all cabinet x-ray systems, indicators shall be provided to show when x-rays are being generated. These indicators shall be legibly labeled "x-ray on".
- There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement, "Caution: X-rays Produced When Energized".
- There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port, a clearly legible and visible label bearing the statement, "Caution: Do Not Insert Any Part of the Body When System is Energized – X-ray Hazard". This requirement has been adopted by most countries.
- Shielding curtains in the port should always be monitored for defects and replaced if necessary.

Radiation meters are tools used for measurement during surveys. There are 3 types of radiation meters to choose from: Scintillation counters, GM (Geiger–Müller) tubes and Ion chambers. Ion Meters are bulky units, have a slower response time and are not recommended for cabinet survey.

The Survey or Critical Inspection is carried out in a smooth sweeping motion at a measured pace. Most radiation meters have a slow response time and you need to note the reading when the needle or counter has stopped climbing, ensuring that the complete surface of the machine has been covered.

Onsite awareness during testing is very important. For example, a machine may test successfully at first and then fails after installation. It necessary to check background radiation, caused by geographic area or adjacent equipment, and subtract it from any readings to obtain the correct result.

To comply with local rules and radiation regulations, market-leading x-ray systems have country-specific sticker and warning labels in the local language applied to the machine and incorporate multiple safety features. These include:

- Tunnel curtains to retain x-ray emissions
- A safety interlock design
- Lockable power isolators
- Accessible emergency stops
- A top-mounted lamp stack with 360-degree visibility.

9. Support from X-ray Equipment Suppliers

X-ray equipment suppliers can support US companies with radiation safety and regulatory compliance by offering radiation safety training packages. Training includes licensing and registration, radiation safety, and development and implementation of a radiation protection program.

In addition, engineers can also perform routine radiation surveys and machine inspections to ensure radiation levels emitted from an x-ray system are within safe working levels and are compliant with local regulations.

Outside the US, engineers can also perform routine radiation surveys and machine inspections to ensure radiation levels emitted from an x-ray system are within safe working levels, but only country-trained engineers can declare a machine compliant with local regulations.

10. Conclusion

As food x-ray inspection systems generate ionizing radiation, their use is highly regulated and it is the owner's responsibility to ensure equipment is safe to use, even if an operator has to stand next to the machine for every hour of the working day.

Safety regulations vary from country to country and from state to state. Europe overall is stricter than the United States or Canada with regard to radiation emission limits.

New x-ray inspection equipment must be registered with the country or state's Radiation Control Agency which involves notifying the Agency of the installation location and date. Equipment must also be installed to comply with local rules and regulations on the use of ionizing radiation for the country in which the machine is being used.

Modern x-ray systems are built to protect users from the effects of radiation and incorporate multiple safety features. In addition, market-leading x-ray equipment suppliers can help companies with radiation safety and regulatory compliance in numerous ways as this white paper shows.

Glossary

SI: The International System of Units (abbreviated SI from the French Système international d'unités) is the most widely used system of measurement. For the purpose of this white paper only the measurement Sievert is used although it is common to use gray (Gy) as the standard unit of absorbed radiation dose (1 Gy = 1 Sv).

A microsievert per hour (µSv/hour) is the SI derived unit of radiation absorbed dose rate.

The sievert (Sv) is the SI derived unit of equivalent radiation dose, effective dose, and committed dose.

A milliroentgen/hour is the derived unit of ionizing radiation dose. 100 milliroentgens equal to 1 millisievert on condition that biological effects of ionizing radiation or other photon radiation, for example gamma radiation, is considered.

Notes

[1] United Nations Scientific Committee on the Effects of Atomic Radiation (2008). Sources and effects of ionizing radiation. New York: United Nations (published 2010), page 3.

[2] Radiation Threats and Your Safety, Armin Ansari, 2010, page 10.

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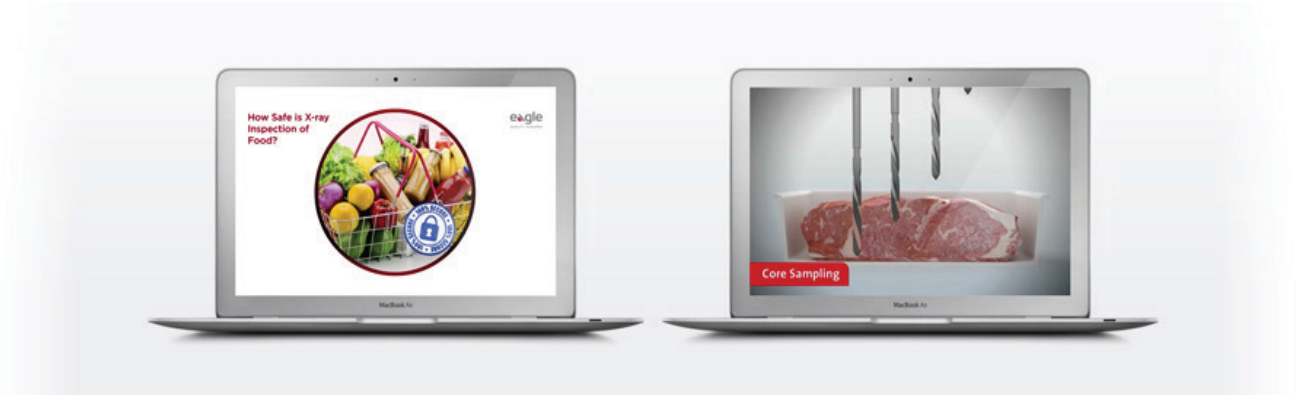

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