Natural Resources for Human Health
eISSN: 2583-1194

Original Research

**Received** 16 April 2026
**Revised** 20 May 2026
**Accepted** 22 June 2026

Natural Resources for Human Health 2026, Vol. 6 (3s): 585–597

**KEYWORDS**:
Radiation Sterilization; ionizing radiation, and non-ionizing radiation.

# A Comparative Review Study of Different Types of Radiation Sterilization Methods

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**ABSTRACT:** This review paper aims to gather information on various radiation sterilization methods to assist in determining which method is appropriate for each application. While the review discusses the primary principles, mechanisms of microbial inactivation, process parameters, material compatibility, and certain uses in the medical, pharmaceutical, and food and consumer product industries, it provides an analysis of the available peer-reviewed literature. Also provided is a detailed analysis of the pros and cons of each sterilization method, along with the impact of various laws and ISO 11137 sections. Review the safety and environmental concerns for each radiation sterilization method. Finally, the review discusses industry trends moving towards alternative methods of sterilization using e-beam and X-ray technologies.

## 1. INTRODUCTION

Industries provide a broad range of products, and sterilization ensures their safety, quality, and efficacy. In healthcare, the sterilization of pharmaceutical products, medical devices, and surgical tools, along with customer safety, helps prevent healthcare-associated infections (HAIs) and is therefore of utmost importance (Sharma et al., 2023). In the food industry, the opposite is also true. To preserve and extend the nutritional value and shelf life of food products and to sterilize them in the food industry, processes such as food irradiation and pasteurization are used (Fifield et al., 2021; Chiozzi et al., 2022). Sterilization in the cosmetic and consumer goods industries is also important. As product complexity and the globalization of supply chains steadily rise, so does the need for robust parental control. The direct costs of HAIs in U.S. hospitals are estimated to range from $28 billion to $45 billion annually, illustrating the staggering economic impact of infections (Stone, 2009). The significant costs incurred from extended hospital stays, additional treatments, and the added morbidity and mortality are captured in the economic impact study of HAIs. This significant financial impact underscores the critical importance of effective sterilization in preventing infections and reducing healthcare costs (Stone, 2009).

For much of history, the two widely accepted methods of sterilization involved thermal (steam and dry heat) and chemical (ethylene oxide and formaldehyde). While effective, both have considerable downsides. One such example is thermal sterilization. The method is incompatible with many sensitive and important materials such as polymers and biologics (Kumar and Rana, 2021). Regarding chemical sterilization, using agents such as ethylene oxide (EtO) exposes workers to a toxic and carcinogenic environment, raising significant environmental and health concerns. Such obstacles are the impetus for the continued search for newer sterilization processes that are as, if not more, effective, and for a greater variety of materials that are more considerate of health and the environment (Pereira et al., 2025).

A powerful and versatile alternative to all of the traditional methods is radiation sterilization. This method, which comprises both ionizing and non-ionizing radiation, is revolutionizing the inactivation of microorganisms by destroying their DNA. Gamma radiation, electron beams (e-beam), and X-rays are the primary ionizing radiation sources used for sterilization. These methods offer benefits, including higher efficacy and deeper penetration, and allow the product to be sterilized in the final packaging. There are guarantees that the product will remain sterile up to the point of use (Silindir and Özer, 2009; Harrell et al., 2018; Huang et al., 2019). Fifield et al. (2021) illustrate how these methods work on various types of polymers used in medical devices. Memarzadeh (2021) cites examples of using ultraviolet (UV) light as a non-ionizing radiation for surface, air, and other types of disinfection. Still, its use is limited due to its poor penetration.

This review paper aims to provide a comprehensive overview of radiation sterilization methods for the first time. It attempts to achieve the following goals:

- Describe the concepts and mechanisms of microbial inactivation for each method of radiation sterilization.
- Describe and compare the merits and demerits of gamma, e-beam, X-ray, and UV sterilization.
- Discuss the impacts of radiation on various materials, including polymers, bioproducts, and food.
- Discuss the application of radiation sterilization in various fields.
- Discuss the control of radiation sterilization, particularly the provisions of ISO 11137.

## 2. HISTORICAL PERSPECTIVE ON STERILIZATION

Over the centuries, the practice of sterilization has progressed greatly, from simple approaches to the more advanced techniques present today. While most ancient cultures had a limited understanding of microorganisms, they relied primarily on heated tools for instrument cleaning. For example, the ancient Egyptians used fire to sterilize surgical instruments, although their understanding of microbial life was limited (Ahmed et al., 2020).

The 19th century marked a shift in the history of sterilization, thanks to the germ theory of disease developed by Louis Pasteur and Robert Koch. Their theory established a link between microorganisms and infectious diseases, leading to greater emphasis on surgical asepsis. Joseph Lister, in the 1860s, was the first to use carbolic acid (phenol) as a surgical instrument disinfectant to clean and post-operative wounds, and his methods greatly reduced the incidence of surgical infections (Milgroom, 2023; Macintyre and Hughes, 2024).

Furthermore, the introduction of the autoclave by Charles Chamberland in 1879 was a major advancement in sterilization technology. The autoclave used pressurized steam to achieve temperatures above boiling, providing an effective, more efficient way to kill microorganisms and the tough, spore-forming bacteria (Blessing et al., 2026). The last century brought several advancements in sterilization methods, including chemical sterilization methods, such as ethylene oxide (EtO) gas sterilization, which is used for heat-sensitive materials, as well as the development of radiation sterilization, which has proven to be an effective method across diverse fields of medicine and industry (Pereira et al., 2025). This historical development indicates the ongoing search for better, safer methods of sterilization, and the advancements in these methods are the focus of the technologies described in this paper.

## 3. FUNDAMENTAL PRINCIPLES OF RADIATION STERILIZATION

In radiation sterilization, energy is used to disrupt microorganisms' cellular functions, rendering them unable to multiply. The success of this method depends on the type of radiation used, the energy level, and the dose administered to the product. Generally, radiation sterilization is classified as either ionizing radiation or non-ionizing radiation (Fairand et al., 2019; Samarth et al., 2020).

### 3.1. Ionizing Radiation

Ionizing radiation can remove bound electrons from an atom, initiating the process of ion creation. This type of radiation is also very effective at eliminating microorganisms' DNA, rendering them ineffective. The main forms of ionizing radiation used in the sterilization process include gamma radiation, electron beam (e-beam) radiation, and X-ray radiation (Munir and Federighi, 2020; McEvoy et al., 2023).

#### 3.1.1. Gamma Radiation

Over the last 40 years, gamma radiation from Cobalt-60 has been one of the most widely used techniques for sterilizing medical tools (O'Hara, 2022).

Produced from the radioactive decay of Cobalt-60, gamma rays are used in medical sterilization. Cobalt-60 is created in nuclear reactors. To provide a steady supply of gamma radiation, Cobalt-60 is trapped in stainless steel devices and placed on a rack inside a shielded cell (Jarrett et al., 2018).

Since gamma rays have deep penetrating power, they interact with matter primarily via the Compton effect. Millions of secondary electrons, responsible for depositing the dose and damaging the biological structures of microorganisms, are produced in such interactions (Maqbool, 2017). Microbial life is also affected by the free radicals produced. Highly reactive hydroxyl radicals form as a result of gamma photons interacting with water in microorganisms. It is a leading factor in DNA damage, as it is also a byproduct of the previously mentioned process (LaVerne, 2000; Shahi et al., 2021).

The amount of radiation given to a product is expressed in kiloGrays (kGy). A dose of 25 kGy is standard for sterilization and is sufficient to achieve a Sterility Assurance Level (SAL) of $10^{-6}$, corresponding to a 1-in-a-million chance of an item being non-sterile (Moldenhauer, 2023). A key challenge in gamma sterilization is 'dosimetry', which involves measuring the radiation dose to the entire product (minimum dose required) and maintaining a maximum dose (maximum dose tolerated) (Fairand et al., 2019).

**3.1.2. Electron Beam (E-beam) Radiation**

In the electron beam (e-beam) sterilization process, microorganisms are inactivated and removed by high-energy, fast-moving electrons. This technique is becoming increasingly popular because of its speed and efficiency (Li et al., 2025).

Electron accelerators in the 50-80 kW range generate E-beams. It is roughly 3.3 to 5.3 million Curies (MCi) of Cobalt-60. These accelerators use electricity to produce a high-energy stream of electrons (Brown, 2022). Basically, electricity creates a stream of high-energy electrons, which are then scanned to form a radiation curtain, allowing items to move along a conveyor. E-beam technology, unlike gamma radiation, does not use radioactive substances (Pillai and Shayanfar, 2016).

E-beam sterilization is a process that exposes microorganisms directly to high-energy electrons, breaking DNA strands and rendering them incapable of reproduction. With extremely high dose rates, exposure time is extremely short, typically a few seconds (Li et al., 2025). Silindir and Özer (2009) conducted a study comparing e-beam and gamma-ray sterilization, finding that e-beam was better because it was faster and didn't require a radioactive source.

The e-beam sterilization process is very precise and extremely controllable, and it's easy to repeat to achieve a specific dose. To achieve a uniform distribution, the sample needs to be irradiated from both sides (Bhat et al., 2021).

**3.1.3. X-ray Radiation**

X-ray sterilization combines the best characteristics of e-beam and gamma techniques, offering speedy turnaround times, good processing flexibility, pallet setup processing, and relatively low dose rates (Malinowski, 2021).

The X-ray radiation occurs when a stream of high-energy electrons is sent towards a dense metal, generally of the kind called tantalum; the electrons lose kinetic energy, and the radiation caused by this energy loss is called either Bremsstrahlung (braking radiation) (Goldstein et al., 2017). At the relevant energies used for sterilization (of the order of 7.5 MeV, in the example given), only 10-15% of the total kinetic energy is converted to radiation, which is a very inefficient process. To irradiate about 1 megacurie of Cobalt-60, about 15 kW of x-ray power is needed, which in turn requires about 120 kW of electron beam power. Like e-beam, x-ray sterilization does not contain radioactive materials (Chmielewski, 2017).

Like gamma rays, X-rays are electromagnetic radiation that penetrates materials and generates secondary electrons, which, in turn, can damage the DNA of living microorganisms. Compared to gamma rays, X-rays provide a more uniform dose distribution (Fan and Niemira, 2020). In a paper, McEvoy et al. (2020) provide a detailed overview of the advantages of X-ray sterilization, especially concerning penetration and dose uniformity [10].

Gamma radiation takes longer to process, resulting in longer sterilization periods, whereas X-ray sterilization offers a higher dose rate. X-ray sterilization also offers greater flexibility, as it can be easily switched on and off, unlike gamma sterilization (Reid and Fairand, 2018).

**3.2. Non-Ionizing Radiation**

Surface and air disinfection are the primary uses of non-ionizing radiation because it lacks the energy to remove electrons and therefore cannot cause ionization (Hitchcock, 2018).

#### 3.2.1. Ultraviolet (UV) Radiation

With wavelengths ranging from 100 to 400 nanometers (nm), Ultraviolet (UV) radiation is a type of electromagnetic radiation. For many decades, it has been used as a non-chemical disinfection method (Koutchma, 2019).

The three major subdivisions of the UV spectrum are UV-A, UV-B, and UV-C. The UV-A spectrum (315 400 nm) is the longest wavelength of ultraviolet radiation, and the ozone layer does not absorb it. The UV-B spectrum (280 315 nm) is the range of UV radiation mostly absorbed by the ozone layer. Finally, UV-C (100 280 nm) is the most effective range for germicidal applications, and is totally absorbed by the atmosphere. The most germicidal wavelength of UV light is 262 nm. Far-UV-C (207-222 nm), a sub-range of UV-C, is radiation that cannot penetrate human skin's outer layers and, therefore, is not harmful to humans (Nishigori et al., 2023). Eadie et al. (2022) conducted a study demonstrating that 222 nm Far-UVC radiation is effective at inactivating airborne pathogens in a chamber the size of a room, suggesting it can be used to disinfect occupied rooms continuously. UV-C can be produced by several artificial electrical devices, such as low-pressure mercury vapor lamps (which emit light at 254 nm, which is nearly the most optimal germicidal wavelength) and excimer lamps (Nishigori et al., 2023).

UV-C radiation disrupts microbial DNA and RNA via photodimerization, in which bonds form between pyrimidine bases. This damage stops the microbes from reproducing (Johann and Molinier, 2020).

In healthcare, laboratory, and food production settings, UV radiation is primarily used to disinfect surfaces and air, as well as treat water. However, its effectiveness is limited to low penetration power, as it cannot penetrate through materials or reach unexposed areas (shadowing) (Albertini et al., 2023).

## 4. COMPARATIVE ANALYSIS OF RADIATION STERILIZATION METHODS

Different radiation sterilization techniques vary in effectiveness, penetration ability, process parameters, material compatibility, and overall performance (Mubarak et al., 2019). This section evaluates the most critical differences among gamma, e-beam, X-ray, and UV radiation sterilization methods.

### 4.1. Efficacy and Microbial Inactivation

The three types of ionizing radiation, gamma, e-beam, and X-ray, are all excellent at inactivating a broad range of microorganisms, including bacteria, viruses, and spores. They primarily work by damaging the DNA of microorganisms, thereby ensuring a high level of sterility. Medical devices must reach a SAL (Sterility Assurance Level) of 10^-6, which all three easily achieve at 25 kGy (Fan and Niemira, 2020).

UV (non-ionizing) radiation is also effective against microorganisms, but because it is primarily used for disinfection, it is less effective than the radiation types above. Its energy is lower than that of the above types of radiation, and its ability to penetrate is also lower, meaning it will primarily be effective against surface or airborne microorganisms and will be ineffective for sterilizing contained or packaged medical devices (Albertini et al., 2023).

### 4.2. Penetration Capability and Dose Uniformity

Another significant attribute that differentiates the various types of radiation is the degree to which they can penetrate a substance. Gamma rays and X-rays are types of electromagnetic radiation, meaning they have high penetrating power, which makes them useful for sterilizing larger, denser, fully packaged items. E-beam sterilization is more cost-effective for low- to medium-density materials. At the same time, it has limitations and lower penetration than gamma or X-rays because it is composed of charged particles rather than electromagnetic energy, and it is more dependent on electron energy and material density (Silindir and Özer, 2009; Beh, 2023).

The next important consideration is the uniformity of dose, defined as the ratio of the maximum to the minimum dose a product has received. E-beam sterilization is the least used because it is single-sided. To achieve acceptable uniformity, products are often irradiated on both sides, unlike gamma radiation sterilization, which is the other extreme. X-ray sterilization generally offers the best dose uniformity (Fan and Niemira, 2020).

### 4.3. Process Parameters: Cycle Time and Throughput

The various methods of radiative sterilization exhibit highly variable processing times and throughputs, resulting in a wide range of outcomes. E-beam sterilization, with a dose rate of about 20 MGy/hr, has a cycle time of a few seconds, allowing it to process high volumes of products. In terms of processing time, X-ray sterilization is faster than gamma radiation sterilization as it has a dose rate about 6 times that of an average gamma facility, allowing processing times in the order of minutes. Of the three methods, gamma irradiation is by far the slowest, with a dose rate of about 10 kGy/hr, meaning that to deliver a dose of 25 kGy it would take between 2.5 and 3 hours (National Academies of Sciences, 2021; McEvoy et al., 2023).

**4.4. Material Compatibility and Effects**

Although radiation sterilization is viewed as a 'cold' process, several radiation-interacting materials undergo a range of alterations in their physical and chemical characteristics. Reaction changes encountered during a sterilization process depend on the type of radiation, the dose, and the specific materials involved (Fairand et al., 2019).

Many polymers used in medical devices are affected by radiation and by the damage caused by sterilization itself (Pérez Davila et al., 2021). Ionizing radiation can cause chain scission (degradation) and cross-linking in some polymers, altering their mechanical properties, such as tensile strength and flexibility. Irradiation of some polymers causes color changes and brittleness. In some cases of e-beam and X-ray irradiation, the high dose rate results in less oxidative degradation than gamma irradiation. It is due to the limited time available for reactions with oxygen; however, the increased temperature within the irradiated polymer can be concerning. For example, a dose of 25 kGy is expected to raise the temperature of the surrounding water by 6°C. With e-beam and X-ray irradiation, the temperature is expected to exceed this level due to rapid energy deposition (Bakai et al., 2022). Azevedo et al. (2025) provide the most thorough review of radiation effects on several thermoplastic polymers and are a good starting point for assessing material compatibility [19]. Additionally, Roxby et al. (2024) studied the effects of gamma and X-ray irradiation on polymer materials used in healthcare and provided aid in determining materials for various sterilization techniques.

The exposure of biologics and tissue allografts to radiation is equally detrimental. For instance, a standard dose of 25 kGy gamma radiation is known to reduce the strength of bone allografts by 20-30% and the work-to-fracture by up to 70% (Rahman et al., 2018). Tendon allografts may also exhibit decreased stiffness and load-to-failure, while the collagen and elastic fibers in the skin and tracheal grafts may undergo damaging alterations. The effects of radiation on tissue allografts were reviewed by Singh et al. in 2016, who recommended careful dose selection to balance the tissue allograft's sterility and biomechanical function (Sawadkar et al., 2025). Nguyen et al. (2007) also documented the effects of gamma irradiation on allograft bone in biological and biomechanical aspects, thereby substantiating the dose-dependent effects of the radiation. Therefore, sterilization techniques and radiation dosage are crucial for protecting sensitive materials; milder-dose techniques and even other modalities may be warranted. (El-Hansi et al., 2020)

**4.5. Overview of sterilization methods**

The following Table 1 summarizes the radiation compatibility of several common polymers used in medical devices:

**Table 1:** The radiation compatibility of several common polymers used in medical devices (Chmielewski, 2017; Malinowski, 2021; Hasan et al., 2024).

| Polymer | Gamma Compatibility | E-beam Compatibility | X-ray Compatibility | Notes |
|---|---|---|---|---|
| Polypropylene (PP) | Fair to Good | Good | Good | Gamma irradiation can make it brittle and discolored. Stabilizers can improve resistance. |
| Polyethylene (PE) | Good | Excellent | Excellent | Generally shows good stability. High-density PE (HDPE) is more resistant than low-density PE (LDPE). |
| Polyvinyl Chloride (PVC) | Poor to Fair | Fair | Fair | Tends to discolor (yellow/brown) and become brittle. |

| | | | | |
|---|---|---|---|---|
| | | | | Requires stabilizers for radiation sterilization. |
| Polystyrene (PS) | Excellent | Excellent | Excellent | High radiation stability due to the presence of aromatic rings. |
| Polycarbonate (PC) | Good | Excellent | Excellent | It can experience some yellowing and a reduction in impact strength. |
| Polytetrafluoroethylene (PTFE) | Very Poor | Poor | Poor | Highly susceptible to degradation by all forms of ionizing radiation. |

Table 2 summarizes the key advantages and disadvantages of the different radiation sterilization methods:

**Table 2:** The advantages and disadvantages of the different radiation sterilization methods (Sarcan and Özer, 2020; Malinowski, 2021; Sharma et al., 2024).

| Method | Advantages | Disadvantages |
|---|---|---|
| **Gamma** | High penetration; well-established technology; suitable for dense products | Slow processing time; uses radioactive source (Cobalt-60); potential for material degradation |
| **E-beam** | Very fast processing time; no radioactive source; precise dose control | Limited penetration; not suitable for very dense or large products; requires product to be irradiated from two sides |
| **X-ray** | High penetration; no radioactive source; good dose uniformity; faster than gamma | High initial capital cost; complex equipment; less established than gamma and e-beam |
| **UV** | No chemicals; low cost; effective for surface and air disinfection | Low penetration; not suitable for packaged products; effectiveness reduced by shadowing |

## 5. APPLICATIONS ACROSS INDUSTRIES

Radiation sterilization is a flexible technology that can be used for various purposes. It can be used for the sterilization of heat-sensitive materials, for sterilizing products in their final packaging, and for quick, cost-effective radiation sterilization, making it an indispensable tool for ensuring product safety and quality (Chmielewski, 2023).

### 5.1. Medical and Healthcare Products

Ionizing radiation is used to sterilize most disposable medical devices, such as surgical gloves, catheters, surgical gowns, face masks, and orthopedic implants (Ozdemir and Kurtuluş, 2025). Gamma and X-ray radiation are effective for terminal sterilization of medical devices, as they can penetrate densely packed medical device kits. For example, we have sterile wound dressings and disposable custom procedure kits. E-beam sterilization is also good for rapid processing and high throughput (Lieberman et al., 2020).

### 5.2. Pharmaceutical Products

In the pharmaceutical sector, radiation sterilization is used to sterilize some drug products, active pharmaceutical ingredients (APIs), and packaging materials. It's especially beneficial for heat-sensitive medications and biologics that can't endure conventional steam sterilization (Rogers, 2025). Radiation sterilization (e-beam) is considered ideal for biologics and pharmaceuticals because of their small size, lightweight nature, and low radiation dose requirements. Nevertheless, for each product, the risk that radiation may cause degradation of the active ingredients or excipients needs to be assessed (Lieberman et al., 2020).

### 5.3. Food Industry (Food Irradiation)

Food irradiation is one of the many ways to ensure the safety of the food we consume by extending shelf life through the use of ionizing radiation to control spoilage and remove foodborne pathogens such as Salmonella and E. coli. In the United States, the Food and Drug Administration (FDA) has approved the irradiation process for several food products, which include but are not limited to, beef, pork, poultry, crustaceans (such as shrimp, lobster, crab), fresh vegetables and fruits, lettuce and spinach, shell eggs, and shellfish (oysters, clams, mussels, and scallops) (Indiarto et al., 2023). Mshelia et al. (2023) reviewed the principles and applications of food irradiation and its potential to mitigate challenges in food safety and security. Food irradiation can also be used to delay sprouting and ripening, as well as to control insect pests in imported fruits. Food irradiation does not make food radioactive, and major public health organizations such as the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have approved it (Thomas, 2020).

### 5.4. Cosmetics and Consumer Goods

During cosmetic production, radiation is used to eliminate pathogens from both raw materials and finished products. This is especially crucial for cosmetics that are used on the skin or around the eyes. Also, radiation is used to sterilize some consumer products (household products and packaging materials) to enhance product safety and extend shelf life (Gupta et al., 2020).

### 5.5. Other Industrial Applications

Aside from the main industries listed above, radiation processing has various other applications in industry. For instance, radiation processing can be used to cross-link polymers, thereby improving their strength and endurance. Also, tissue allografts used in transplantation can be sterilized, and archival materials and artifacts in museums can be decontaminated. Gamma irradiation is also used to sterilize certain types of labware, which are made of temperature-sensitive plastic like Styrene (Grzelak et al., 2023; Zhang et al., 2024)

## 6. REGULATORY LANDSCAPE AND VALIDATION STANDARDS

Radiation used for sterilization is also highly controlled to ensure safety and the effectiveness of the sterilized product. Therefore, it is controlled by both international and national guidelines. Such regulation is necessary to establish confidence in the whole sterilization process and to promote international commerce (Fairand et al., 2019).

### 6.1. The ISO 11137 Standard for Radiation Sterilization

The main applicable international standard for radiation sterilization of health products is ISO 11137. This regulation is comprehensive enough to cover all the steps involved in the development, validation, and maintenance of control over the radiation sterilization process. Furthermore, this regulation is comprised of three main sections and one additional technical specification that also falls under ISO 11137 (Venugopal et al., 2022):

ISO 11137-1: Requirements includes a set of specifications relating to each stage of the radiation sterilization process; process definition, validation, and routine monitoring, and includes the establishment of the maximum acceptable dose, which is the dose at which the product's characteristics would be considered unacceptably changed, and the determination of the sterilization dose, which is the dose which is required to achieve the specified SAL (Venugopal et al., 2022). It includes gamma, e-beam, and X-ray radiation and describes the manufacturer's obligations to ensure the sterility and safety of their product(s) (Huang, 2022).

ISO 11137-2: Establishing the Sterilization Dose describes in detail the minimum sterilization dose required to achieve the desired Sterility Assurance Level (SAL). It discusses various dose setting methodologies, including Method 1, which consists of several verification dose trials to find the necessary dose to deactivate a population of resistant microorganisms, and Method VDmax, a simplified method to validate a predetermined dose (e.g., 25 kGy or 15 kGy) based on the bioburden data (Moldenhauer, 2023). The Hansen et al. (2020) study illustrates the principle' dose is dose', showing that no matter which radiation source is used, the absorbed dose will always determine the extent of microbial inactivation.

ISO 11137-3: Guidance on Dosimetric Aspects offers guidance on the dosimetric aspects of radiation sterilization. It provides the user with everything needed to select, calibrate, and use dosimetry systems, as well as to conduct dose-mapping studies to identify the minimum and maximum dose zones within a product (Johnson et al., 2024).

In ISO/TS 13004:2013: Guidance on the selection of a sterilization process, a technical specification is provided to help select the most suitable sterilization process for a health care product. It weighs the pros and cons of various sterilization techniques, including radiation, and guides users in making risk-based decisions (Cobos et al., 2018).

### 6.2. Role of the FDA and Other Global Regulatory Bodies

Radiation sterilization is also used in accordance with other internationally accepted practices, such as ISO 11137, while alternative methods are being developed and used to sterilize medical devices and pharmaceuticals (Jacobs, 2021). In the U.S., the FDA regulates the sterilization of medical devices and pharmaceuticals. The FDA considers ISO 11137 a consensus standard, meaning all producers are expected to comply with its guidelines. The FDA also regulates the use of radiation above a certain threshold for specified uses, e.g., food irradiation, and establishes the maximum radiation dose (including irradiation) for various food items (Natividade et al., 2023).

It is also true in other regions of the world, where individual regulatory authorities, such as the European Medicines Agency (EMA), establish sterilization requirements and ensure compliance. The unification of such national standards with ISO 11137 is of paramount importance for the uniformity of sterilization validation worldwide and for international trade in sterilized items (Ilyas et al., 2024).

## 7. SAFETY AND ENVIRONMENTAL CONSIDERATIONS

Any sterilization technology must be assessed for its effects on human safety and the environment. Although the advantages of radiation sterilization are numerous, the safety and environmental concerns associated with its use are significant and must be carefully addressed (Jildeh et al., 2021).

### 7.1. Occupational and Public Safety

Worker and public safety are the top priorities for radiation facilities. For example, gamma irradiation facilities use large amounts of radioactive Cobalt-60, which means they need heavy shielding and strict security measures to prevent anyone from touching the source, as well as shielding walls to prevent exposure. Additionally, the movement and final disposal of these sources include security and logistical problems (Ramamoorthy et al., 2024). Bennett (1998) focuses on irradiation plants and their environmental impacts, and provides details on how to manage the environment when dealing with radioactive sources (Bais et al., 2018).

On the other hand, e-beam and X-ray facilities can be switched off and do not require radioactive sources, so they do not need to worry about radiation exposure during maintenance or downtime. However, they do need shielding, and UV shielding must be used to protect staff (Lieberman et al., 2020). Exposure to UV radiation can increase the risk of radiation injury to staff. Protection and exposure in controlled areas are required to reduce the risk of injury (Robinson et al., 2023).

### 7.2. Environmental Impact and Sustainability

Considering the effects of sterilization technologies and their environmental impact is of growing importance. For gamma irradiation, the reliance on Cobalt-60 is an issue. Cobalt-60 is a non-renewable resource, meaning it has a limited supply worldwide. The production and disposal of radioactive isotopes are environmental concerns connected to the management of nuclear waste (Pereira et al., 2025).

Because e-beam and x-ray sterilization do not produce radioactive waste and are powered by electricity, they are generally considered more environmentally friendly. It is even though the e-beam and x-ray sterilization facilities have a higher overall energy consumption. In fact, when a radioactive source is compared to an e-beam or X-ray source, the expected environmental impact is lower. It is even more true when the radioactive source is used close to deadlines. The shift to using renewable energy is expected to have a positive impact on these sterilization technologies (Lieberman et al., 2020). Janiaczyk et al. (2022) note that the e-beam sterilization process is safe because it uses no radioactive materials, and the source can be turned off when not in use.

## 8. FUTURE TRENDS AND CONCLUSION

New technologies, as well as updated regulations or laws, will create demand for new methods that provide safe and effective sterilization. It has and will continue to play a critical role in the rapid growth of the sterilization industry (Aljasham et al., 2024).

### 8.1. Advances in Radiation Technology

Radiation tech continues to evolve due to ongoing advancements in research and development. An example of this is Far-UV-C light, which can be used for continuous disinfection of occupied spaces, as it can inactivate pathogens while leaving human skin unharmed (Memarzadeh et al., 2021). Additionally, advances in accelerator technology are increasing the compactness, efficiency, and cost-effectiveness of e-beam and X-ray systems, broadening their potential uses (Clarke et al., 2022).

**8.2. The Shift Towards Alternative Modalities (X-ray and E-beam)**

A trend becoming apparent in the market is the increased preference for e-beam and X-ray sterilization over gamma irradiation (Edgecock and Chmielewski, 2025). It is due to the concerns regarding the long-term safety and availability of Cobalt-60, radioactive source management issues, and the need for more environmentally friendly and versatile sterilization methods. It is where X-ray technology shines, providing the same high level of penetration as gamma rays and the added benefit of being non-radioactive (Praveen et al., 2025).

## CONCLUSION

Radiation sterilization is among the most adaptable technologies, ensuring safety and quality across diverse domains. This review analyzes the different methods of radiation sterilization and compares their advantages and disadvantages. Gamma, e-beam, and X-ray radiation differ in their effectiveness, penetration, processing speed, effect on materials, and required processing infrastructure. Also, UV radiation is not a sterilization method, but it is useful for disinfecting surfaces and the air.

Choosing the best radiation sterilization method depends on product characteristics, required throughput, and the applicable regulatory framework. Given the industry's evolution, the adoption of sustainable, flexible technologies such as X-ray and e-beam technologies will likely dominate. Thus, knowledge of the principles underlying the various radiation modalities is important for the safe and effective sterilization of products.

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