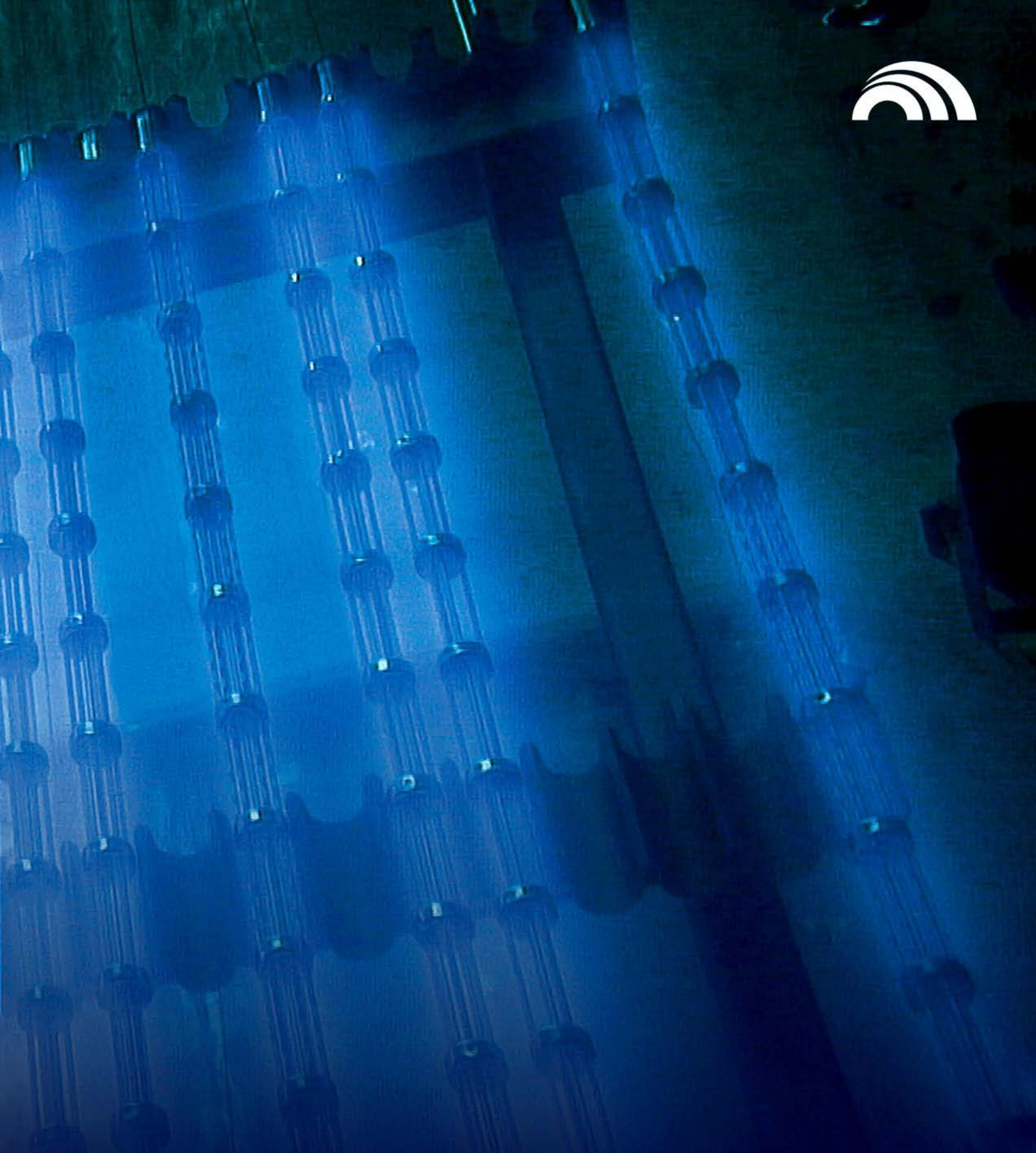


DOE | MARKET RESEARCH STUDY
COBALT-60 ALTERNATIVE EQUIPMENT

Image courtesy of Bruce Power

Table of Contents

1.0 Introduction

The National Academies of Sciences, Engineering, and Medicine (the National Academies) were tasked by Sandia National Laboratories with assessing the status of medical, research, sterilization, and other commercial applications of radioactive sources and alternative (nonradioisotopic) technologies in the United States and internationally. The purpose of the study was to support existing and future activities under the National Nuclear Security Administration Office of Radiological Security program to reduce the current use of high-risk radiological materials in these applications and promote use of alternative technologies.[1]

> *"The Office of Radiological Security (ORS) within the Department of Energy's (DOE's) National Nuclear Security Administration (NNSA) expanded the focus of its efforts from encouraging voluntary physical protection measures of radiation sources to include promoting alternative technologies. ORS is charged to "work with government, law enforcement, and businesses across the globe to protect radioactive sources used for medical, research, and commercial purposes; remove and dispose of disused radioactive sources; and reduce the global reliance on high activity radioactive sources through the promotion of viable nonradioisotopic alternative technologies. As an update to NAS's 2008 report of the same title, the ORS requested that the National Academies review and assess developments in radioactive source applications and feasible alternative technologies for replacing the radioactive sources currently used in those applications."*[2]

Radiological source replacement falls under the umbrella of non-proliferation. The goal is to work with industries that currently use radiological source material and help them find replacements that are effective, but do not require the use of radiological materials. Sample applications include insect sterilization, numerous medical applications, linear accelerators and others. NNSA's Defense Nuclear Nonproliferation (DNN) R&D and ORS's strategy supports the adoption and development of non-radioisotope devices to achieve permanent risk reduction by reducing the footprint of risk-significant radiological Materials.

NNSA Office of Defense Nuclear Nonproliferation R&D is looking for industries where substantial radioactive elements, such as cobalt-60 (Co-60), are being acquired, typically for use as high energy gamma radiation that they naturally emit as part of natural radioactive decay. One solution is to replace the radioactive sources in these industries with alternative technologies that can produce x-rays or electrons. This report examines technologies to replace risk-significant radioactive sources integral to industrial, medical, and research applications with a particular focus on the customers for the sterilization of Medical Device and Pharmaceutical, Food, and Industrial Radiography. Additionally, this report considers some of the commercial barriers to transitioning to nonradioisotopic replacements for high energy gamma radiation sources in these business categories.

2.0 Irradiation and Sterilization in the Medical Industry

The process of irradiation sterilization uses ionizing radiation, such as gamma rays, x-rays, or electrons to sterilize objects. In the process it kills germs that can cause disease and neutralizes other harmful organisms. It inactivates microorganisms very efficiently and, when used for product wrapping, ensures that healthcare products are safe and can be relied upon. As per the International Atomic Energy Agency (IAEA), "Radiation is a safe and cost-effective method for sterilizing single-use medical devices such as syringes and surgical gloves. One of its key advantages is that it allows already-packaged products to be sterilized. A variety of life-saving equipment is sterilized with radiation."[3] Radiation sterilization is used when the device, drug, component, or food is sensitive to heat and moisture and when it needs to be terminally sterilized. That is, the completed product is inserted into its final packaging where both are simultaneously sterilized by radiation exposure.

A key advantage of radiation in the medical field is that it allows already-packaged products to be sterilized.

There are currently three sources of high energy ionizing radiation used for radiation sterilization, ***gamma rays, X-rays, and electrons***. The process is relatively straightforward, the object (packaged or unpackaged) that needs to be sterilized, is exposed to a defined dose of ionizing radiation. The ionizing radiation breaks molecules in a cell or virus which results in the death of a contaminating microorganism, rendering the irradiated product sterile. Approximately 50% of medical devices that are sterilized globally are sterilized by ionizing radiation and the remainder are sterilized by exposure to ethylene oxide vapor.

2.1 Gamma Irradiation

Gamma irradiation exposure is the most commonly used method of irradiation sterilization. Here, the gamma rays are generated through the natural radioactive decay of Cobalt-60 to Cobalt-59. The decay process releases two high energy photons (gamma particles) which are capable of penetrating most material and killing any living tissue or organism that they encounter. Gamma sterilization takes place on a large industrial scale globally in specialized, highly regulated facilities. The facilities are designed to thoroughly expose the product to a sterilizing dose of gamma radiation while completely protecting the facility and surrounding from accidental gamma exposure.

The heart of the gamma irradiation facility is the Co-60 radiation source. The source is composed of a rack of sealed stainless-steel tubes that contain Co-60 slugs or pellets. The rack is large enough that pallets of material can be irradiated in one or two passes. The composition of an industrial Co-60 source rack can be seen in the image below.

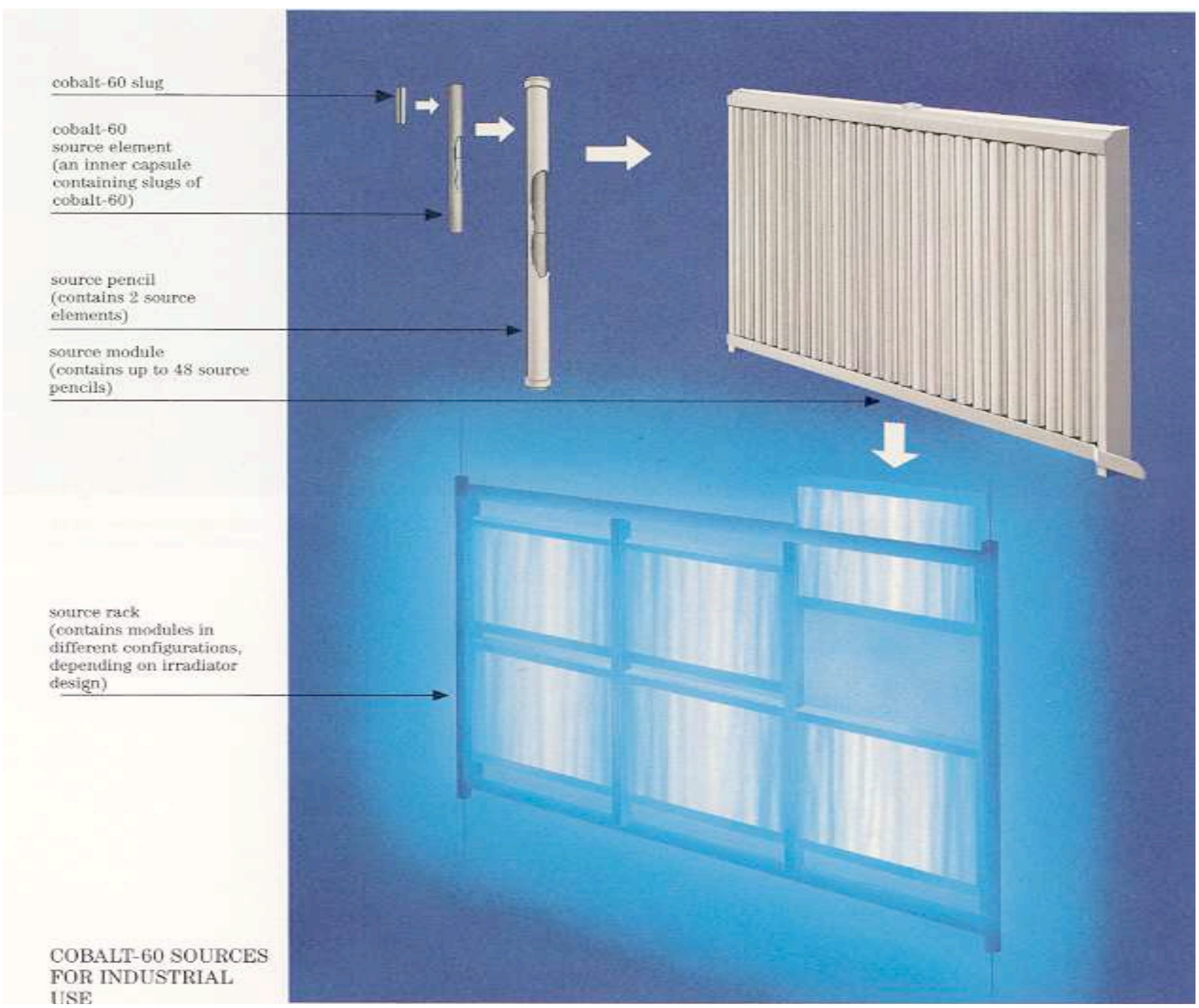


Figure 1: Industrial Co-60 Source Rack
Source: Cobalt-60 source for industrial use[4]

Gamma radiation is always "on", that is, gamma radiation will continue to be generated until all the Co-60 decays to Co-59. To allow for entry into the chamber and to control the dose of radiation a particular item will receive, the source rack is kept in a water storage pool at the facility to prevent the gamma radiation contamination of the facility and facility personnel. When materials need to be sterilized, the source rack is raised from the pool to allow direct contact with the emitted gamma radiation. Additionally, the water also assists with cooling of the source. One can see the rack under water in this diagram of a prototypical gamma sterilization facility:

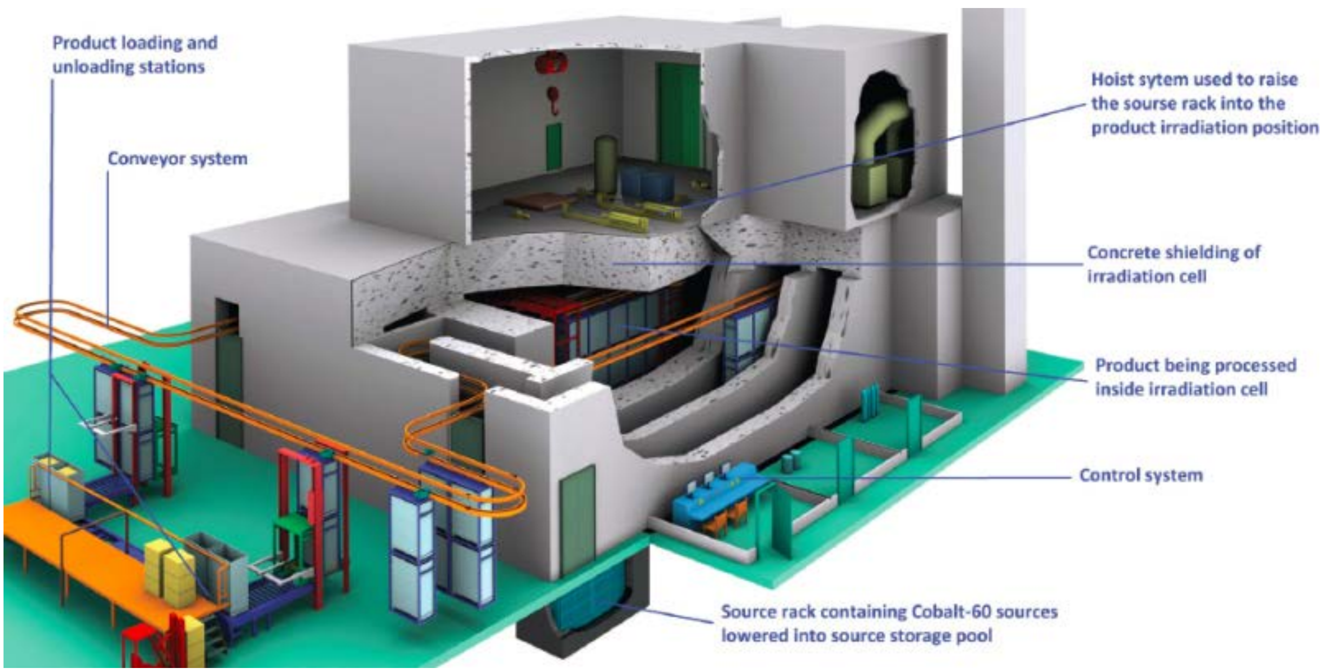


Figure 2: Prototypical Gamma Sterilization Facility Gamma Irradiation Facility[5]

Due the penetrating power of gamma radiation, a properly designed gamma irradiation facility can sterilize large quantities of product at one time in their final packaging configuration. A few points of interest:

- The area of the facility where sterilization takes place prevents the release of any gamma radiation into the rest of the facility and the environment.
- The gamma radiation is not powerful enough to penetrate the nucleus of atoms so, it cannot make anything radioactive, including the materials being sterilized.
- Because the gamma rays are the result of the radioactive decay of Co-60, eventually, the Co-60 source needs to be periodically recharged and eventually entirely replaced. This occurs when the available gamma radiation levels drop below an effective sterilizing dose.

- The decayed Co-60 sources are removed and stored until they are safe for disposal. Or they are sent to a few specialized nuclear reactors for replenishment. In the reactor, the Co-59 in the sources is bombarded with neutrons, eventually reforming Co-60.

Next to ethylene oxide exposure, gamma irradiation exposure is the most common means of sterilizing medical devices and/or medical device components.

2.2 X-ray Irradiation

X-ray irradiation is a direct substitute for gamma irradiation in terms of efficacy, material penetrating capabilities, material compatibility and sterilization load size. Like gamma rays, x-rays are photons albeit at lower energy level. An x-ray irradiation facility has many similarities to a gamma sterilization facility. These include:

- A shielded area where the x-ray irradiation will take place. The shielding will protect the facility operators and the surrounding environment.
- A conveyer system that takes non-sterile pallets of products into the irradiation chamber. The conveyer system returns the sterilized pallets of product back to facility for shipping back to the customer.

The key differences are:

- The x-rays are generated by a linear accelerator coupled to an x-ray converter. Here, a linear accelerator generates a powerful electron beam (e-beam). The beam is focused on a dense piece of metal known as a target (i.e., tantalum or tungsten). When struck by the e-beam, the target gives off x-rays. These are the x-rays that are used to sterilize products. Note, there is no gamma radiation generated. And the x-ray irradiator is "on/off". That is, when the power is off, no x-rays are generated.
- There is no cooling pool. The x-ray generator generates heat only when in use. It is cooled through an internal cooling system.
- It uses a much greater amount of electricity to operate the linear accelerator to generate the x-rays. The gamma irradiators require electricity only to operate the facility.

Compared to gamma irradiators, linear accelerators require electricity to generate the X-rays.

The following figure is a diagram of a prototypical x-ray irradiation facility. Note, the Rhodotron is a proprietary linear accelerator manufactured by IBA Industrial Solutions, Belgium.

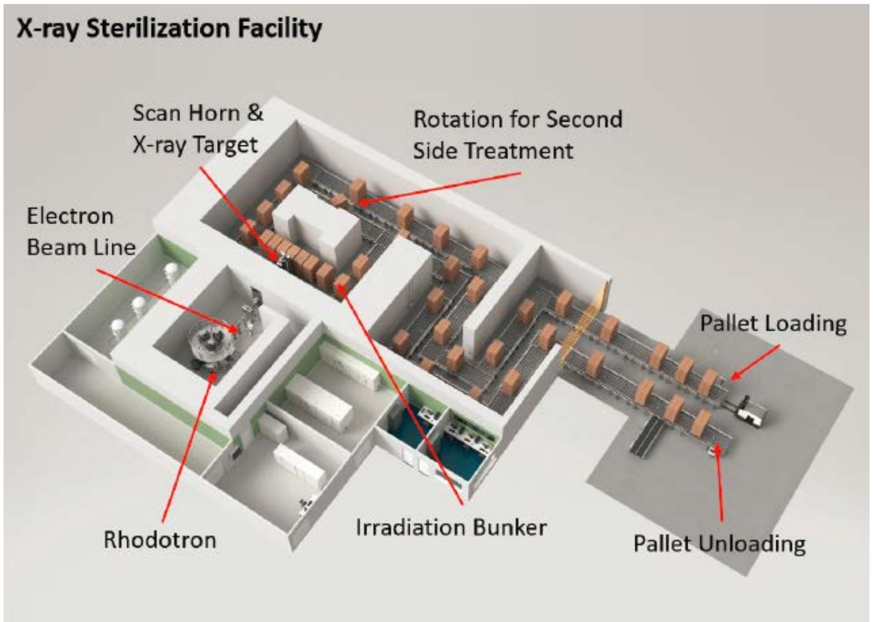


Figure 3: X-ray Sterilization Facility[6]

Currently, x-ray irradiation accounts for less than 1% of medical device sterilization. This is primarily due to lack of facilities, perceived operating expense overages when compared to gamma and e-beam sterilization facilities as well as regulatory/market forces all contribute to momentum against switching sterilization methods for marketed products and components. From a construction and operational cost point of view, new x-ray and Co60 facilities over a 10-year period will be similar. The high cost of electricity for operation and cooling in the x-ray facility is off set by the cost to replenish the Co60 sources.[7]

2.3 Electron Beam (e-beam) Irradiation

Electron beam (e-beam) irradiation is well established as a method for sterilizing products. Unlike gamma irradiation and x-ray irradiation where the irradiating source is the ionizing power of high energy *photons*, e-beam sterilization involves exposing the product to a focused beam of high energy *electrons*. Although the particles are different, the outcome is the same, the molecules in microorganisms are ionized causing them to break or change shape. This leads to cell death, rendering the product sterile. Below is a diagram of an e-beam sterilization facility:

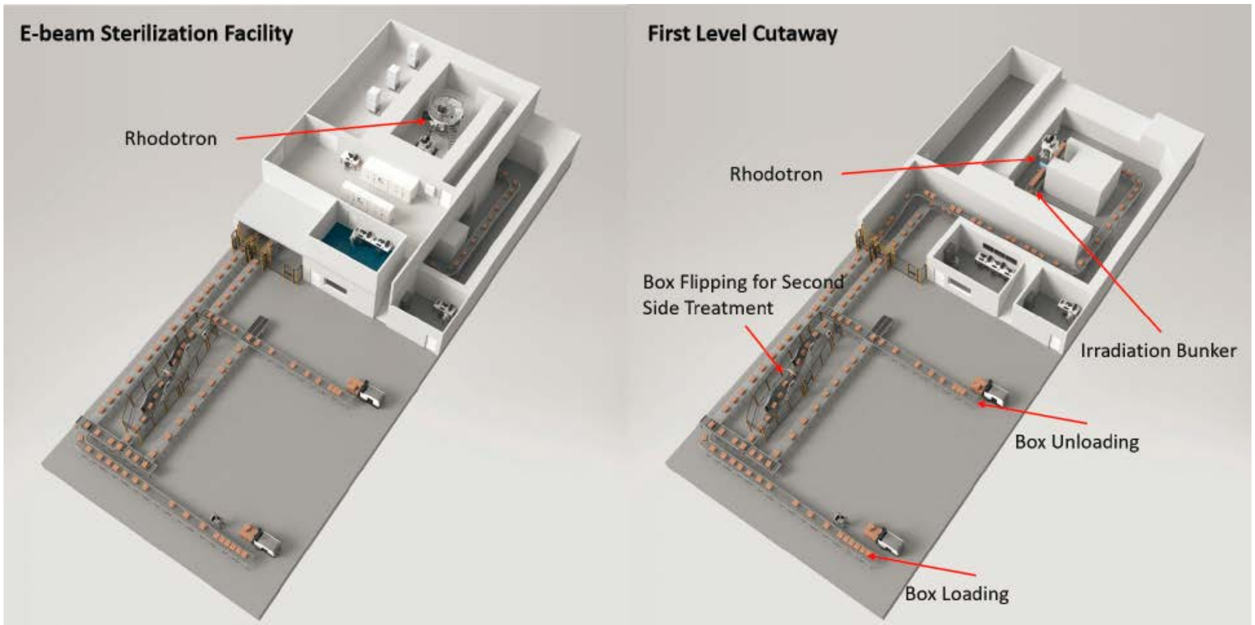


Figure 4: Prototypical E-beam Sterilization Facility[8]

Note, a Rhodotron is the source of the electron beam. Here it is used to directly sterilize the products. In x-ray sterilization, the Rhodotron is used to generate the x-rays which sterilize the product.

Some key differences between e-beam and gamma/x-ray irradiation are:

- The e-beam has limited penetration. This means that boxes of product are the largest thing that can be sterilized. From a practical point of view, a pallet of boxes must be unpacked and put through the e-beam one at a time, then repalletized for return to the customer. With both gamma and x-ray, entire pallets of product can be unloaded, irradiated and reloaded for return to the customer.
- The e-beam can sterilize much faster than can gamma and x-ray irradiation. This increase in throughput can offset the cost of only being to sterilize one box at a time.
- Due to an e-beam's limited penetration capability, e-beam facility requires significantly less shielding than that of a gamma/x-ray irradiation facility. An e-beam facility will be much cheaper to construct than a gamma/x-ray irradiation facility.

From a practical point of view, a pallet of boxes must be unpacked and put through the e-beam one at a time, then repalletized for return to the customer.

E-beam irradiation accounts for approximately 10% of medical device and component sterilization. The number of e-beam facilities is growing to meet the sterilization demands of the medical device industry.

Key differences between gamma, x-ray and electron beam sterilization can be seen in the table below:

Table 1: Major Differences - Gamma, X-Ray, and Electron Beam Sterilization

Source	Electron Beam @ 10 MeV	Gamma Rays with Co60	X-Rays @ MeV
Penetration	Limited: one side about 350 mm at density 0.1	big (entire pallet); big (entire tote)	very big (up to **entire pallet**)
Homogeneity (DUR)	good to average: ~1.5 (one side) to 2.8 (double side treatment)	Good: (~1.5 for pallets of 400 kg); **very good** (+1.3-1.5 for boxes)	**very good**: (+1.3 for pallets of 400 kg)
Economic	varied (very good to poor)	good	good
ISO 11137 accepted	yes	yes	yes
Tolerance for inhomogeneity	small, poor	good	**very good**
Ozone impact	small	big	small (close to E-beam)
Heat development	treatment room is cold. Add ~5°C/10 kGy/h dose	treatment room is -~5°C. Add ~5°C/10 kGy dose.	treatment room is cold. Add ~5°C/10 kGy dose. Max temp much lower than in Gamma.
Type. dose rate	~500 - 30'000 kGy/h (part of box under treatment)	~0.5 - 20 kGy/h (~20 pallets under treatment)	~100 - 500 kGy/h (part of pallets under treatment)
Polymer acceptability	good	limited	good

Source: Steris Applied Sterilization Technologies[9]

2.4 Regulatory Requirements for Medical Device Sterilization

Medical device sterilization is a regulatory requirement and is the final step in the manufacturing of healthcare products such as medical protective barriers, including personal protective equipment,[10] procedure kits and trays, implants, syringes, catheters, and wound care products.[11] Within the pharma industry, drug products such as active pharmaceutical ingredients, prefilled syringes, drug components, excipients and primary packaging and components are also sterilized. A broad range of single use, prepackaged medical products, as well as certain consumer products, are required by government regulations to be sterile, or meet certain acceptable microbial levels when sold. Products are treated as part of the production process either in-house by the manufacturer or an outsourced sterilization provider.

There are >60 commercial scale gamma processing facilities in the U.S. and more than 200 worldwide. X-ray is a newer technology and currently accounts for <1% of medical device sterilization volume. Gamma processing is robust, widely available, and reliable.[12] Nordion estimates that 50% of single use devices in North America are sterilized with ethylene oxide, 40% with gamma and 10% with other modalities such as X-ray and electron beam.

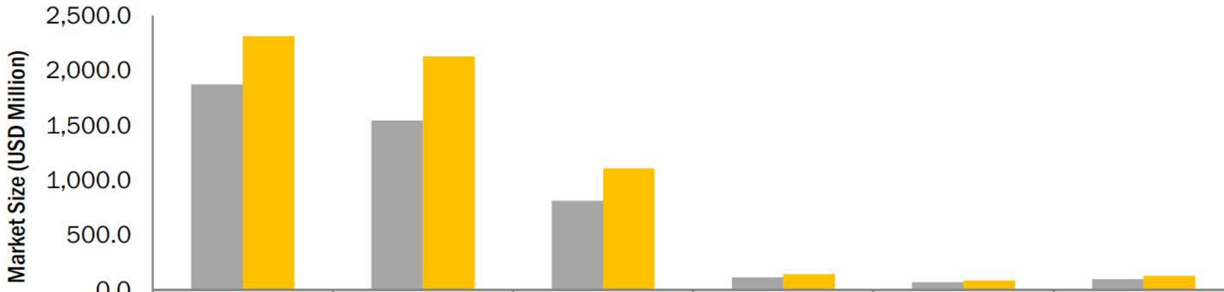
2.5 Medical Devices Sterilization Trends

The medical equipment and supplies manufacturing industry is comprised of 5,176 establishments across the United States as of 2017.[13] Some of these companies are also global entities[14] that have manufacturing and distribution sites located throughout the world.[15] A small number of medical device manufacturers use their own in-house sterilization facilities to sterilize a portion of their products. However, only the largest suppliers of medical devices and other products can cost-effectively sterilize any portion of their products in-house. Many companies outsource this service. The different sterilization methods used by contract manufacturers include ethylene oxide (EtO),[16] gamma irradiation, electron beam (E-Beam) irradiation, nitrogen dioxide, and other methods. Given short-term and long-term concerns with both EtO and gamma irradiation methods, X-ray sterilization, also known as X-ray irradiation processing, has emerged as an alternative method. It is gentler on polymeric materials than gamma irradiation, and it does not have the emission dangers of EtO.[17]

Figure 5: What is the best sterilization Method?
Source: Medical Device Academy. Click here to see video

In the forecast below, EtO is projected to remain the leading global sterilization method, despite environmental concerns. There are 86 EtO commercial sterilizers across the United States. In April 2023, EPA proposed new requirements for these facilities. These requirements, if implemented, will reduce the amount of EtO that comes out of commercial sterilizers by 80% and will reduce risk in nearby communities. The Federal Register Notice, "Proposed Air Toxics Rule for EtO Sterilization Facilities," was soliciting public input. Estimated capital costs for emissions reductions range from $146 million - $308 million. Qualitative information gathered on the industry by EPA "suggests that demand for EtO sterilization services may be fairly inelastic, meaning demand may be insensitive to price changes and potential price increases could have minimal impact on the equilibrium quantity of products sterilized with EtO. Since demand for medical devices and healthcare services are generally considered inelastic, demand for EtO sterilization services may also be inelastic given how critical it is as an input for medical devices."[18] As noted in the following figure, globally, ethylene oxide sterilization is the most frequently used method.

The demand for ethylene oxide (EtO) sterilization services may be fairly inelastic and insensitive to price changes.



	Ethylene Oxide (EtO) Sterilization	Gamma Sterilization	Electron-beam Radiation Sterilization	X-ray Irradiation	Steam Sterilization	Other Methods
2022	1,871.4	1,541.0	809.5	112.0	69.9	97.7
2027	2,311.9	2,124.0	1,106.1	142.6	85.2	126.1
CAGR	4.3%	6.6%	6.4%	5.0%	4.0%	5.2%

Figure 6: Global Sterilization Services Market, by Method, 2022 vs. 2027 ($ Million)

Source: Reprinted with permission from MarketsandMarkets, January 2023

The global projections for the growth of the various sterilization services by method are based on historical data (2018-2020) with 2021 as the base year. It is important to note that during these years (2018-2021) COVID was at its height, which globally increased the use of gamma radiation and the desire for one-time use in packaging which maintained the high use of EtO. Investment in X-ray did increase during this period, however as relatively few X-ray devices are approved for commercial use, this did not have an impact on this projection.

Key trends include projected increase in the use of plastics, medical device manufacturing and outsourcing of sterilization services. Each of these is discussed below.

2.5.1 The Medical Device Market

The global medical device market is estimated to have a conservative value of $471.5B in 2023 to reach in excess of $564B in 2027, growing steadily to register a conservative CAGR of 4.4% between 2022-2027.[19]

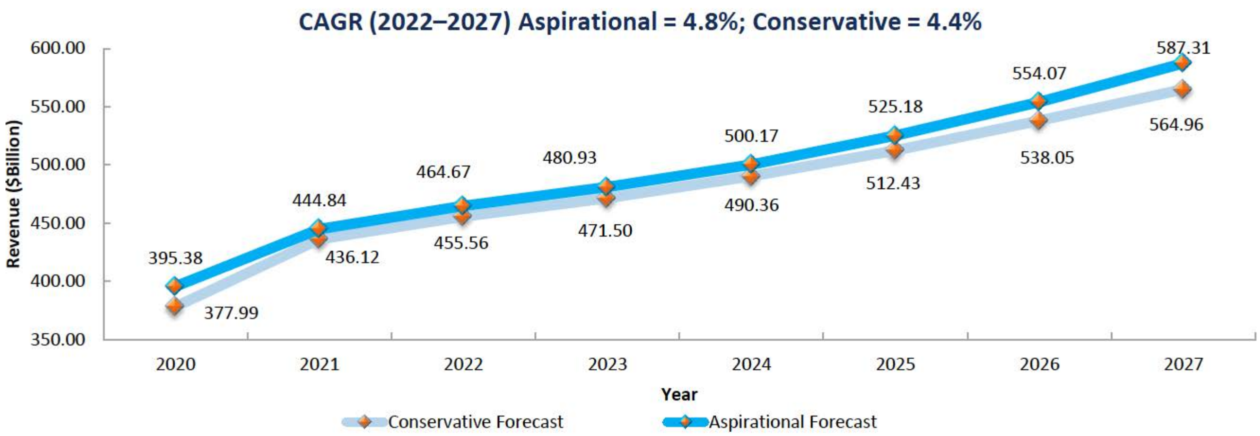
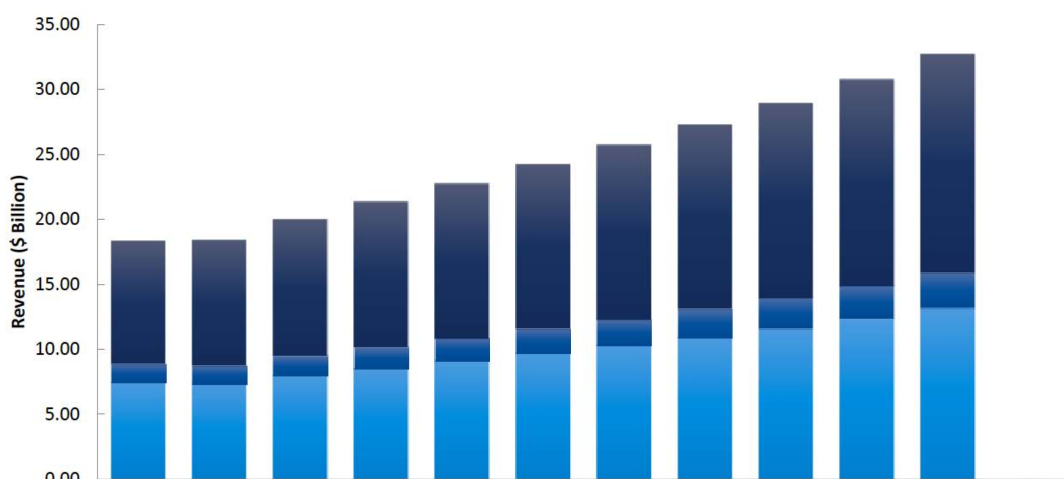


Figure 7: Global Medical Devices Revenue Forecast, 2020-2027

Source: Reprinted with permission form Frost & Sullivan, April 2023

2.5.2 Trends in Medical Plastics

The global market for medical plastics is predicted to grow at a compound annual growth rate (CAGR) of ~6.3% over the 2022–2029, from ~ $21.3 billion in 2022 to reach ~$ 32.7 billion in 2029. Overall consumption of plastics in medical applications is increasing. Packaging accounted for the largest share in 2022, a trend that is projected to continue through 2029. Packaging products, such as prefilled syringes, bottles, jars, vials, tubes, cartridges, ampoules, adapters, beakers, containers, and caps and closures, are seeing increased demand, which in turn, creates a demand for medical plastics.[20]



	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	CAGR (2022–2029)
Healthcare Packaging	9.50	9.69	10.51	11.21	11.91	12.65	13.41	14.19	15.00	15.90	16.83	6.0%
P&Is	1.41	1.37	1.49	1.62	1.75	1.89	2.03	2.19	2.35	2.53	2.72	7.7%
DEIs	7.44	7.34	7.98	8.52	9.08	9.67	10.28	10.91	11.58	12.34	13.16	6.4%

Year

P&Is - prosthetics and implants; DEIs - medical devices, equipment & instruments

Figure 8: Medical Plastics Market:
Revenue Forecast by End Products, Global, 2019-2029

Source: Frost & Sullivan, 2023

There is increasing concern about the amount of single-use plastic used by the medical industry – even though its benefits are clearly understood. The average waste per hospital patient is estimated to be 25 pounds per day. According to the World Health Organization, roughly 55% of hospital waste is plastic with a recycling rate of 20%.[21] Hospitals are being encouraged to improve their associated waste management processes.

2.5.3 Sterilization Services - Outsourcing

According to a 2017 publication, the medical equipment and supplies manufacturing industry is comprised of approximately 5,176 establishments across the U.S.[22] Some of these companies are also global companies[23] that have manufacturing and distribution sites located throughout the world.[24] A small number of medical device manufacturers use their own in-house sterilization facilities to sterilize a portion of their products. However, only the largest manufacturers of medical devices have in-house sterilization capabilities. Many companies outsource this service. Contract sterilization services vary depending on the compatibility of the medical devices with the method and regulatory requirements for the device to be certified sterile. Several medical device manufacturers, hospitals, pharmaceutical companies, and contract manufacturing companies are increasingly outsourcing their sterilization service to third-party providers. Customers purchase gamma sterilization services from suppliers located near their manufacturing or distribution sites in order to minimize transportation costs and turnaround times.[25]

The following table indicates the industry trend and shows that U.S. manufacturers and other customers are shifting more of their sterilization needs to contract providers, rather than increasing their use of in-house sterilization. In 2021, the U.S. off-site sterilization services segment accounted for the largest share or more than 80% of the market. This market is projected to reach $~1.65 billion by 2027 up from $~1.38 billion in 2022, at a CAGR of 3.7 % for the five years 2022-2027. Market drivers include advantages of off-site sterilization over in-house sterilization, rising focus on cost-containment, an increasing number of contract sterilization service providers offering better services to clients, and government regulations for maintaining high standards in sterilization processes. The on-site sterilization services segment is projected to grow from $287 million in 2022 to $323 million by 2027, at a CAGR of 2.4% during the forecast period 222-2027. Growth drivers include less quantity/sterilization required for sterilization and increase in the quality and effectiveness of sterilization.[26]

Table 2: **U.S.** Offsite / Onsite Sterilization Services Market, by Mode of Delivery, 2022 Vs. 2027 (USD Million)

U.S.	2022	2023	2024	2025	2026	2027	CAGR (2022–2027)
Offsite	1,376.2	1,450.8	1,530.2	1,582.2	1,628.5	1,654.1	3.7%
Onsite	287.12	298.77	310.94	317.65	322.75	323.47	2.4%

Source: Reprinted with permission from MarketsandMarkets, January 2023

2.6 Sterilization Methods

Medical devices are sterilized using various techniques including: (1) heat, (2) low-temperature, (3) ionizing radiation, and filtration sterilization. Heat sterilization is performed mainly using moist or dry heat. Low-temperature sterilization is a sterilization process mainly utilized for heat-sensitive devices (heat and moisture-sensitive surgical instrumentation, implants, and medical devices made of heat-sensitive materials) that may be damaged during steam sterilization. This method is non-toxic and includes ethylene oxide, hydrogen peroxide, low-temperature formaldehyde, ozone-based, and other low-temperature sterilization instruments.[27] The ecosystems is shown in the following figure.

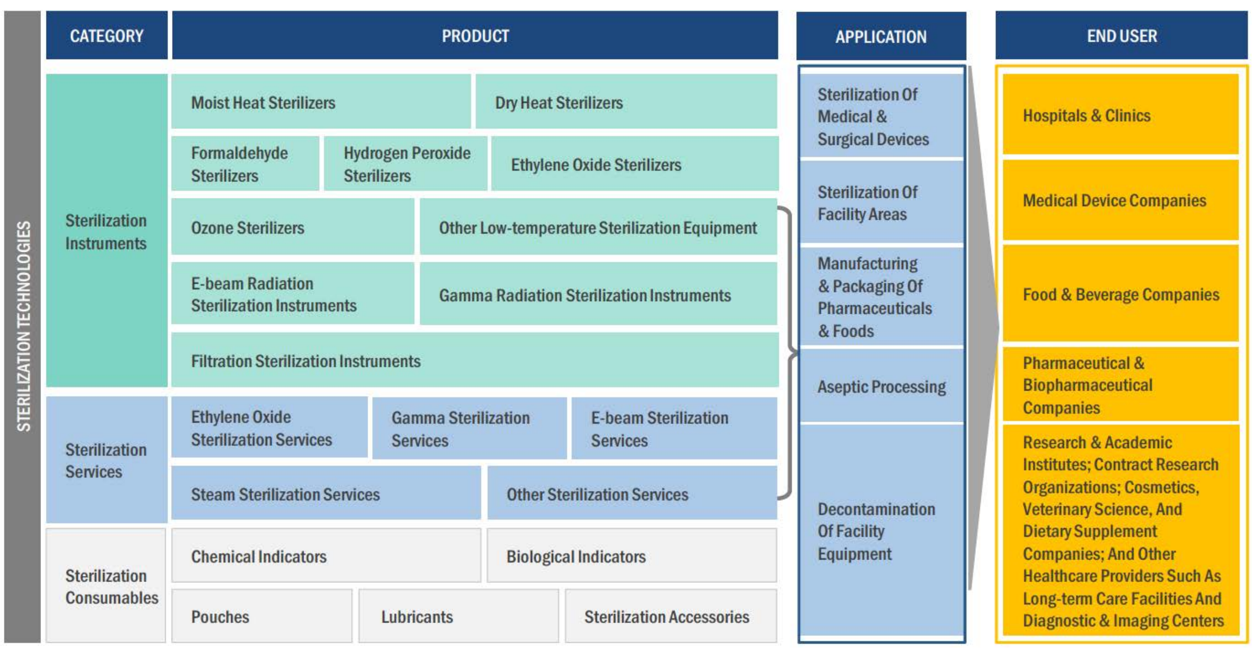


Figure 9: Sterilization Instrument Market

Source: Reprinted with permission from MarketsandMarkets, 2022

The different sterilization methods used by manufacturers include ethylene oxide (EtO),[28] gamma irradiation, electron beam (E-Beam) irradiation, nitrogen dioxide, and other methods.

Table 3: Medical Devices Sterilization Methods

Method	Application
Gamma Irradiation	Sterilization of medical instruments and single-use medical supplies, such as syringes, surgical gloves, gauze, catheters, IV sets, and labware Pressure-sensitive packaging Pre-treatment and microbial reduction of raw materials
Electron Beam Irradiation	Sterilization of medical instruments and single-use medical supplies, such as administration kits, wound dressings, IV syringes, dialysis products, and catheters
X-ray Irradiation	Sterilization of medical instruments and single-use medical supplies, such as IV sets, syringes, catheters, surgical gloves, gauze, and labware
Ethylene Oxide Sterilization	Sterilization of medical devices manufactured from materials whose physical properties degrade with heat or irradiation Custom procedure kits

Source: Reprinted with permission from MarketsandMarkets, 2022[29]

2.6.1 X-ray Radiation Sterilization

X-ray radiation sterilization is the closest substitute for gamma sterilization. Steris's website includes a guide for their customers where X-ray is used for sterilization including medical devices, pharmaceutical products, packaging materials, raw materials , cosmetics and polymer modification.[30] X-ray sterilization offers comparable, and possibly superior, depth of penetration, allowing it to compete for products that customers currently sterilize with gamma radiation.[31] X-ray sterilization combines the best features of e-beam and gamma sterilization and is a highly similar photon-based technology to gamma, employing the same units of dose. It is expected to impact and sterilize polymers via the same fundamental physics mechanisms.[32] It offers the depth of penetration of gamma radiation, which makes it suitable for sterilizing dense products and packaging, with the quick turnaround times of e-beam sterilization. Both x-ray and gamma sterilization services are suitable for the same high-density, heterogeneous products.[33] X-ray sterilization services will likely be able to sterilize a number of products as well as, or better than, the gamma sterilization services these products rely on today, including orthopedic implants, liquids, other dense products, impermeable and boxes of that have densities.[34]

To expand the use of X-ray sterilization, several requirements need to be met including "Peer-reviewed verification data. In quality risk management for biopharmaceuticals, trust the science, but verify is key."[35] In addition, the "ISO

10993 standard provides the requirements for sterilizing medical devices with X-rays, but many regulators are unfamiliar with X-ray sterilization."[36]

2.6.2 Electron-beam (E-beam) Irradiation

Electron-beam (E-beam) irradiation is a technique commonly used to sterilize pharmaceutical packaging products and medical devices. This sterilization has the advantage of providing quick-turn terminal sterilization with simple, clean, on/off technology. Some of the players provide E-beam contract sterilization services are Cretex Companies, Inc., E-BEAM Services, Inc., Sotera Health Company, and Avantti Medi Clear (Mexico). Mevex, a STERIS subsidiary manufactures e-beam sterilization systems.

Companies offering E-beam contract sterilization services include Cretex, E-BEAM Services, Sotera Health and others.

In North America, single use, medical device sterilization uses the following technologies:[37]

1. Cobalt-60 Gamma: ~ 40% of volume processed.
2. Ethylene Oxide (EO): ~ 50% of volume processed.
3. E-Beam (accelerator based): ~ 10% of volume processed.
4. X-Ray (accelerator based): ~ <1% of volume processed.

Primary methods of sterilization currently used in the United States include gamma radiation, e-beam radiation, and EO gas. Medical device irradiation constitutes a significant share of the sterilization marketplace. Given short-term and long-term concerns with both EtO and gamma irradiation methods, X-ray sterilization, also known as **X-ray irradiation processing, has emerged as an alternative method.** In 2021, the electron-beam radiation sterilization segment accounted for a 17.8% share of the sterilization services market. This segment is projected to reach $330.5 million in 2027, up from $268.3 million in 2022, at a CAGR of 6.4% for the five years 2022-2027. Although e-beam has been available for thirty years, it still lags behind gamma radiation. The X-ray projected to reach $~$55.5 million in 2027 up from $47.6 million in 2022, at a CAGR of 6.4% for the five years 2022-2027. The gamma sterilization segment is projected to register the highest CAGR of 4.6% for the five years 2022-2027.[38]

Table 4: United States Sterilization Services Market, by Method, 2022 – (USD Million)

Technology	2022	2023	2024	2025	2026	2027	CAGR (2022–2027)
Ethylene Oxide	694.9	722.8	752.2	767.4	779.0	780.4	2.3%
Gamma radiation	588.8	626.1	665.9	694.5	720.8	738.2	4.6%
Electron beam	268.30	284.31	301.36	313.02	323.83	330.50	4.3%
Steam sterilization	31.829	33.100	34.448	35.168	35.678	35.729	2.3%
X-ray radiation	47.64	49.92	52.31	53.74	54.95	55.48	3.1%
Other methods*	31.85	33.38	35.03	36.04	36.92	37.23	3.2%

**Other sterilization methods include vaporized hydrogen peroxide, NO2, peracetic acid, dry heat sterilization, ozone, and hydrogen peroxide plasma gas.*

Source: Reprinted with permission from MarketsandMarkets, January 2023

Market drivers include high product compatibility, extensive and positive history, and wider applications in sectors such as life sciences (microbiological lab equipment), medical devices (disposables), biologics, pharmaceuticals, and other applications. In addition, gamma sterilization is performed after the products are packed in final containers, product sterility is maintained indefinitely as long as the packaging is intact. However, MarketsandMarkets suggest future growth of this segment will be subject to the availability of Co-60, stringent validation rules, and environmental and transportation issues. For many products, manufacturers are required to include the specific facility used to validate a product's listing in the Food and Drug Administration (FDA) (or foreign equivalent) product registration and are typically required to re-register if they switch facilities, making switching locations for a particular product a difficult and expensive process.[39] In addition, significant improvements have been implemented at Co-60 facilities to address security threats and be more efficient with usage of Co-60.[40]

Future growth of the medical device sterilization market is subject to the availability of Co-60, stringent validation rules, and environmental and transportation issues.

2.6.3 Sterilization in the Pharmaceutical Market

Sterilization is an integral part of finished pharmaceutical products and is necessary for the complete destruction or removal of all microorganisms (including spore-forming and non-spore-forming bacteria, viruses, fungi, and protozoa) that can contaminate pharmaceuticals or other materials. Various methods of sterilization are used in pharmaceutical companies, such as heat sterilization, gaseous sterilization, filtration sterilization, and radiation sterilization. Ethylene oxide sterilization, and radiation sterilization techniques are widely used in the pharmaceutical industry for the sterilization of drug-device combinations and active pharmaceutical ingredients, tissues, pharmaceutical manufacturing disposables, prescription pharmaceuticals, ointments, solutions, containers, drug delivery systems, cleanroom garments and supplies, labware, desiccants, excipients, and bulk raw materials such as talcum powder, kaolin, vegetable fibers, and coloring agents.[41] The cosmetics and nutraceutical industries also mainly focus on the sterilization and safety of manufactured products, as the products remain in direct contact with skin and other body parts. To achieve effective sterilization, cosmetic and nutraceutical companies use fogging with sporicidal agents, such as hydrogen peroxide/peracetic acid blends or chlorine dioxide.[42] Markets & Markets estimates the global value of this market to reach ~1.6B in 2023 and is projected to grow at a CAGR of 18.8% from 2023 to 2028 (Table below).

Table 5: Global Nonthermal Pasteurization Market for Pharmaceuticals and Cosmetics, 2023-2028 (USD Million)

Region	2023	2024	2025	2026	2027	2028	CAGR (2023–2028)
North America	28.93	34.59	41.42	49.69	59.70	71.86	20.0%
Europe	11.28	13.18	15.43	18.09	21.24	24.99	17.2%
Asia Pacific	7.42	8.75	10.33	12.22	14.48	17.19	18.3%
South America	1.53	1.73	1.96	2.22	2.52	2.87	13.4%
RoW	0.80	0.89	1.00	1.12	1.26	1.42	12.1%
Total	**49.96**	**59.14**	**70.13**	**83.34**	**99.21**	**118.33**	**18.8%**

Source: Reprinted with permission from MarketsandMarkets, April 2023[43]

According to MarketsandMarkets, Medical Device and Pharmaceutical/Biotechnology Companies comprise over half of the sterilization services now and continuing through 2027. The pharmaceutical & biotechnology companies segment is projected to register a CAGR of 5.0% for the five years, 2022-2027. The medical device companies segment accounted for the largest share of the sterilization services market in 2021. This segment is also projected to register the highest CAGR of 5.9% during the forecast period, 2022-2027. Other end users of sterilization services include the food & beverage industry, the cosmetic industry, dietary supplement manufacturers, the veterinary industry, and other healthcare providers, such as long-term care facilities and diagnostic & imaging centers.

Table 6: Global Sterilization Services Market by End User, 2022-2027 (USD Million)

End User	2022	2023	2024	2025	2026	2027	CAGR (2022-2027)
Medical Device Companies	1,865.0	2,006.1	2,153.5	2,280.4	2,388.7	2,481.4	5.9%
Hospitals & Clinics	1,559.3	1,672.8	1,791.1	1,891.7	1,976.3	2,047.6	5.6%
Pharmaceutical & Biotechnology Companies	690.9	737.3	785.3	825.0	857.4	883.7	5.0%
Other End Users	386.3	410.4	435.2	455.2	471.0	483.3	4.6%
Total	4,501.4	4,826.6	5,165.1	5,452.3	5,693.3	5,896.0	5.5%

Source: Reprinted with permission from Markets & Markets 2022[44]

2.6.4 Food Sterilization

About 600 million people per year become ill because of unsafe food. There are over 200 diseases caused by unsafe food, ranging from abdominal pain to cancers. Food sterilization methods include thermal and nonthermal processes. Thermal food pasteurization technologies lead to changes in product characteristics such as flavor, color, texture, and nutritional value due to the application of heat. Non-thermal pasteurization methods include high-pressure processing (HPP), pulse electric field (PEF), microwave volumetric heating (MVH), ultrasonic, irradiation, and other techniques.[45] Nuclear techniques play an important role in laboratory services to analyze food products for safety and control purposes, and in food processing, such as food irradiation to maintain quality, prevent foodborne illness, reduce food losses and extend product shelf-life.

Figure 10: Food Irradiation and the Changing Climate, IAEA
Source: Click here to see video

Cobalt 60 is used in microbial reduction and microbial remediation services for food and agricultural products including cannabis.[46] Generally, in a microbial reduction process, products are exposed to lower levels of treatment than in a sterilization process. This process is intended to reduce the number of viable organisms and extend shelf life in a wide array of products such as spices, herbs, animal feed and food packaging materials. Irradiation safeguards against bacteria from the time of the packaging.

One recent development for the food irradiation market was the Food and Drug Administration (FDA)'s approval of irradiation for fresh and frozen fruits & vegetables to control pathogens and codified in Code of Federal Regulations, CFR Title 21, Subchapter B, Part 179 Subpart B, "Radiation and Radiation Sources." Ionizing radiation for treatment of foods is limited to:[47]

1. Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.
2. Electrons generated from machine sources at energies not to exceed 10 million electron volts.
3. X rays generated from machine sources at energies not to exceed 5 million electron volts (MeV)
4. X rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

Under current FDA rules, foods that have been irradiated must bear both a "Radiation" logo and a statement that the food has been "treated with radiation" or "treated by irradiation." In addition, "the logo shall be placed prominently and conspicuously in conjunction with the required statement."[48] The FDA approval of irradiation for certain food is expected to drive the growth of the food irradiation market, as it will help food manufacturers meet the increasing demand for safer and healthier food products. In addition, several government organizations, including the WHO and the International Atomic Energy Agency (IAEA), have been promoting the use of food irradiation as a safe and effective method of improving food safety and reducing foodborne illnesses. For example, in 2021, an IAEA coordinated research project (June 21 – August 2026) is demonstrating the feasibility of using low energy electron beams and low energy X-rays to reduce infestation and microbial contamination.[49]

Per the National Academy of Science's report on Radioactive Sources, "Most food and agricultural products treated by irradiation are processed in facilities using gamma radiation from cobalt-60. These facilities typically are not dedicated facilities, but instead multipurpose facilities primarily used for medical device sterilization. At a recent symposium, it was stated that the use of gamma irradiation for food poses security, economic, and availability challenges; that multipurpose facilities are typically optimized for medical device sterilization; and that the technology is not well suited for countries where food security remains an issue. As a result, fewer cobalt-60 facilities are being built for food irradiation.[50]

Note, internationally, US Department of Agriculture (USDA) has eight cobalt-60 facilities and one e-beam facility for phytosanitary processing of food and food ingredients.[51] An interagency agreement between USDA and DOE to transfer these to x-ray or e-beam operations could be considered. This could serve as a pilot to encourage greater adoption of gamma alternative irradiation technologies for the phytosanitary processing for the food processing industry.

Internationally, USDA has eight cobalt-60 facilities and one e-beam facility for phytosanitary processing of food and food ingredients.

The global non-thermal pasteurization market for food and beverages is projected to grow from ~$2.23 in 2023 and reach ~$.56B by 2028. The food segment is the largest application among and is valued at ~$1.6B in 2023.[52]

Table 7: Global Non-Thermal Pasteurization Market, by Application, 2023-2028 (USD Million)

Application	2023	2024	2025	2026	2027	2028	CAGR (2023–2028)
Food	1,637.5	1,956.4	2,341.2	2,806.0	3,368.5	4,050.1	19.9%
Beverages	594.0	713.0	857.6	1,033.3	1,247.3	1,508.4	20.5%

Source: Reprinted with permission from MarketsandMarkets, April 2023[53]

Based on techniques, the non-thermal pasteurization market is segmented into high-pressure processing (HPP), pulse electric field (PEF), microwave volumetric heating (MVH), ultrasonic, irradiation, and other techniques. The HPP segment is expected to continue its growth trajectory in the coming years, driven by the increasing demand for safe and convenient food products and the adoption of this technology in other industries. The global irradiation market is projected to reach $~$597M by 2028 up from $271M in 2023.

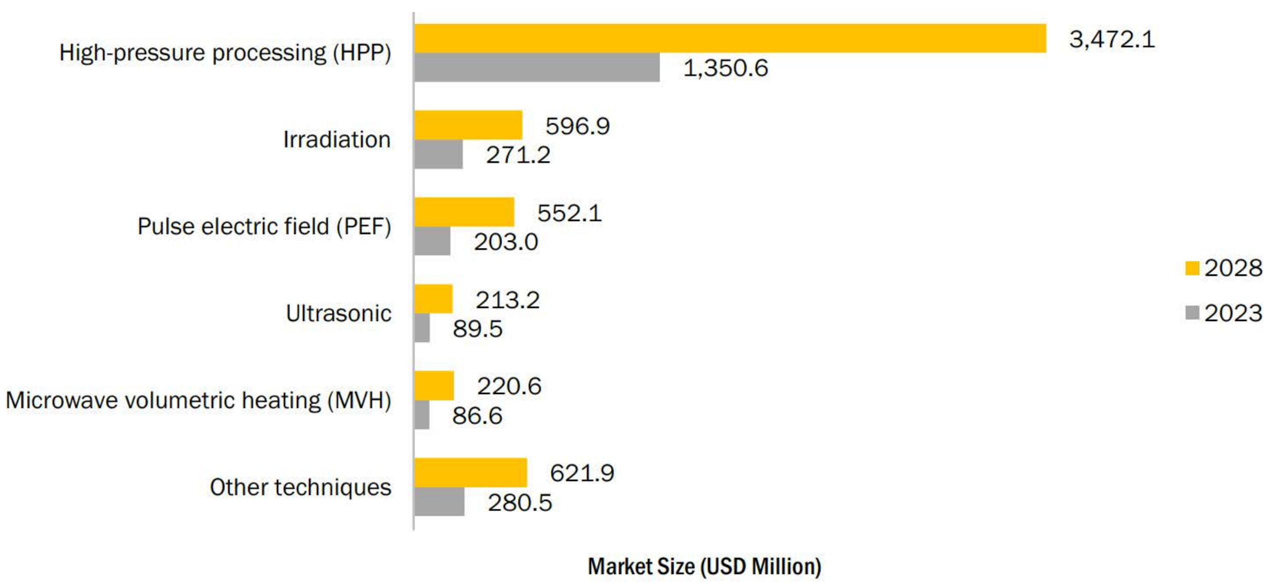


Figure 11: Global Non-Thermal Pasteurization Market by Technology

Source: Reprinted with permission from MarketsandMarkets, April 2023[54]

With respect to the U.S irradiation pasteurization market (including food, beverage, pharmaceuticals and cosmetics), MarketsandMarkets expects it to generate $175.5M in 2028 up from $81.1M in 2023, at a CAGR of 22% during the seven years, 2022 – 2028. At the same time, irradiation is projected to grow exponentially, at a CAGR of 16.7% during the seven years, 2022 – 2028.

Table 8: U.S.: Non-Thermal Pasteurization Market, by Technique, 2023-2028 (USD Million)

Technique	2023	2024	2025	2026	2027	2028	CAGR (2023–2028)
High-pressure processing (HPP)	407.9	497.5	606.9	740.3	903.5	1,103.1	22.0%
Pulse electric field (PEF)	60.1	73.4	89.9	110.2	135.3	166.4	22.6%
Microwave volumetric heating (MVH)	26.4	32.1	39.0	47.5	58.0	71.0	21.9%
Ultrasonic	14.9	18.1	22.0	26.8	32.6	39.9	21.8%
Irradiation	81.1	94.3	109.9	128.2	149.9	175.5	16.7%
Other techniques	87.9	103.6	122.2	144.3	170.8	202.6	18.2%
Total	**678.4**	**819.0**	**989.8**	**1,197.4**	**1,450.2**	**1,758.4**	**21.0%**

Source: Reprinted with permission from MarketsandMarkets, April 2023[55]

2.7 Sterilization Equipment Market

A September 2022 report projects that the global sterilization equipment market (for all applications) will reach ~$11B million in 2027 up from ~$7.3B in 2022, at a CAGR of 8.5% during the 6 years, 2022 -2027. Ionizing radiation is projected to reach ~$1B million in 2027 from ~$1.7B in 2022, at a CAGR of 9.8% during the 6 years, 2022 -2027.[56]

Table 9: Global Sterilization Instruments Market by Type, 2020-2027 (USD Million)

Type	2020	2021	2022	2023	2024	2025	2026	2027	CAGR (2022–2027)
Heat/High-temperature Sterilization Instruments	2,639.35	2,679.91	2,858.36	3,062.45	3,295.87	3,559.55	3,857.80	4,195.67	8.0%
Low-temperature Sterilization Instruments	2,428.19	2,498.88	2,685.77	2,899.92	3,145.49	3,424.30	3,741.31	4,102.45	8.8%
Ionizing Radiation Sterilization Instruments	952.84	992.57	1,075.92	1,171.64	1,281.71	1,407.28	1,550.76	1,715.05	9.8%
Filtration Sterilization Instruments	668.24	677.40	718.49	765.56	819.44	880.26	949.02	1,026.81	7.4%
Total	6,688.62	6,848.76	7,338.54	7,899.57	8,542.51	9,271.39	10,098.89	11,039.98	8.5%

Source: Reprinted with permission from MarketsandMarkets, 2022

Market drivers include regulations by regulatory bodies such as the FDA, the rising incidence of hospital-acquired infections, the growing number of surgical procedures, increase in geriatric population, increasing incidence of chronic diseases, the increasing focus on food sterilization and disinfection, growth in the pharmaceutical and biotechnology industries.[57]

Two radiation ionizing methods used in sterilization are gamma and E-beam. Gamma radiation has the largest market share, projected to grow from ~725.7M in 2023 to more than $1B in 2027. E-beam sterilization is expected to almost double from $350M in 2020 to $~679M in 2027. E-beam is an uneconomical alternative for the vast majority of products that are sterilized with gamma radiation. Indeed, although e-beam has been available for thirty years, it still lags behind gamma radiation.

Table 10: Global Ionizing Radiation Sterilization Instrument Market, by type, 2020-1027 (USD million)

Type	2020	2021	2022	2023	2024	2025	2026	2027	CAGR (2022–2027)
Gamma Radiation Sterilization Instruments	601.10	622.29	670.53	725.72	788.97	860.84	942.56	1,035.64	9.1%
E-beam Radiation Sterilization Instruments	351.74	370.28	405.39	445.92	492.74	546.44	608.20	679.41	10.9%
Total	952.84	992.57	1,075.92	1,171.64	1,281.71	1,407.28	1,550.76	1,715.05	9.8%

Source: Reprinted with permission from MarketsandMarkets, 2022

In terms of regions, North America (for both gamma and E-beam) is growing at a projected CAGR of ~7.1% between 2022-2027. Please note that North America includes Canada, the U.S. and Mexico.

Table 11: Gamma Radiation Sterilization Instruments Market, by Region, 2020-2027 (USD Million)

Region	2020	2021	2022	2023	2024	2025	2026	2027	CAGR (2022–2027)
North America	273.38	281.71	298.53	317.56	339.11	363.16	390.00	419.97	7.1%
Europe	173.21	180.87	197.26	216.09	237.78	262.59	290.99	323.59	10.4%
Asia Pacific	119.17	124.03	136.55	151.00	167.72	186.96	209.16	234.80	11.5%
Latin America	23.55	23.86	25.85	28.13	30.73	33.72	37.11	40.99	9.7%
Middle East & Africa	11.79	11.82	12.34	12.94	13.63	14.41	15.30	16.29	5.7%
Total	601.10	622.29	670.53	725.72	788.97	860.84	942.56	1,035.64	9.1%

Source: Reprinted with permission from MarketsandMarkets, 2022

Drivers for radiation ionizing sterilization market growth include high product compatibility, extensive and positive history, and wider applications in sectors such as life sciences (microbiological lab equipment), medical devices (disposables), biologics, pharmaceuticals, and other applications. In addition, gamma sterilization is performed after the products are packed in final containers, product sterility is maintained indefinitely as long as the packaging is intact. However, MarketsandMarkets suggests that the future growth of this segment will be subject to the availability of cobalt-60, stringent validation rules, and environmental and transportation issues. For many products, manufacturers are required to include the specific facility used to validate a product's listing in the FDA (or foreign equivalent) product registration and are typically required to re-register if they switch facilities, making switching locations for a particular product a difficult and expensive process.[58]

2.8 Areas of Research

There are ongoing research studies to determine the effects of gamma, e-beam, and X-ray irradiation on polymers used in the medical industry in 2020, the IAEA launched a Coordinated Research Project (CRP)entitled "Radiation Effects on Polymer Materials Commonly Used in Medical Devices (F23035)" to advance an understanding of radiation effects on polymer materials commonly used in medical devices. The study compared the effects of gamma, e-beam, and X-ray irradiation on polymers commonly used in the medical industry, including low-density polyethylene, polypropylene, poly (ether-block-amide) thermoplastic elastomers, polytetrafluoroethylene, and others. This study is timely given that medical plastics are largely used across the healthcare sector for manufacturing diagnostic and therapeutic medical devices, equipment, surgical/non-surgical instruments, labware, prosthetics, implants, and healthcare packaging products.[59]

Leonard S. Fifield, and colleagues in the research article entitled, "Direct Comparison of Gamma, Electron Beam and X-ray Irradiation Doses on Characteristics of Low-density Polyethylene, Polypropylene Homopolymer, Polyolefin Elastomer and Chlorobutyl Rubber Medical Device Polymers," identify a potential issue in sterilization of polymers. They state,

> "There is a growing need for increased efficiency in the sterilization of single use medical devices and other products that contain polymer components. Gamma radiation is widely used for devices suited for radiation sterilization; **however, safety, throughput and cobalt-60 source availability are challenging the prospect of relying on gamma radiation to meet the anticipated needs of the industry.** Use of electron beam (e-beam) and X-rays as alternatives to gamma for radiation sterilization have been hampered in part by a concern that these modalities may adversely affect polymer integrity and performance relative to the gamma method, for which the industry has had much more experience."

After testing a variety of irradiation sources on the plastic-properties of various common polymeric packaging materials they concluded:

> "Both e-beam and X-ray appear as viable alternatives to gamma irradiation for sterilization of the polymers. However, the manufacturers must be aware of the impacts of sterilization radiation on the polymers in their devices due to the potential of sterilization dose levels to affect the molecular structures of polymers."[60]

One of the obstacles to transitioning to non-radiological sources identified in the literature is the *knowledge gap*, specifically related to materials. A 2017 Fermi National Accelerator Laboratory report entitled, "Accelerator-driven Medical Sterilization to Replace Co-60," highlights some of the gaps, concluding:

> "… there is a knowledge gap in how the different radiation sources (Co-60, e-beam and X-ray irradiation) affect common medical device materials. Because of this, irradiation effects on materials for all three modalities need to be documented in peer-reviewed references and made publicly available to encourage use of different irradiation modalities."[61]

This issue was also highlighted in a recent IAEA Consultancy Meeting Report entitled "Radiation effects on polymer materials", which concluded:

> "Additional studies, expanding on those existing to date, should be considered in order to further educate the sterilization community. This education includes facilitating awareness of the similarities, as well as the differences, between a product's critical performance attributes when sterilized using different sources of ionizing radiation. These different sources can be the three irradiation modalities, or simply a significantly different dose rate within the same modality. These studies can still focus on the dominant polymers used, but could also investigate biopolymers (e.g., biodegradable polyesters like Polylactic Acid, Polyglycolic Acid, polysaccharides, and collagen). Bioresorbable implants sterilization or crosslinking applications such as for ultra-high molecular weight polyethylene (UHMWPE) are of particular interest, where differences in irradiation conditions are expected to introduce a significant difference in critical attributes of products. Such effects are believed less likely to occur for the majority of product currently sterilized using ionizing radiation.
>
> The effect of additives (e.g., antioxidants, stabilizers, friction lubricant, plasticizers), mainly present in dominant polymers, should also be considered (investigation of radiation-induced by-products and/or leachables)."[62]

Overall, the IAEA suggested:

> "… there are two main areas that can be improved in the radiation processing community – scientific knowledge and improved accessibility of information on accelerator-based sterilization processes. Due to gaps in data, processes and knowhow, adoption of e-beam and X-ray sterilization has suffered despite their acceptability in the pertinent regulations and standards. Improvement in these areas is important because it directly involves the health and safety of hospital patients and consumers of health care products and can affect the future availability of alternative sterilization technologies that can solve potential capacity issues with 60Co and EO.
>
> There are numerous published studies on the effects of radiation on the various types of polymers; however, it was concluded that interested individuals find it difficult to find publications relevant to their needs, especially for e-beam and X-ray radiation. The influence of dose rate on polymer effects is one area in particular that needs additional study."[63]

Note, each manufacturer of plastic and plastic parts for use in medical devices relies on the use of a proprietary additive package to ensure performance during manufacturing processing and use in a final form. Evaluating the impact of irradiation sources on plastic performance needs to look beyond the polymers themselves and look at the impact on the mechanical and chemical properties of the final plastic form. Future studies should involve the plastic suppliers in developing the sterilization conditions for each gamma, x-ray and e-beam that allow for equal performance.

3.0 Key Players

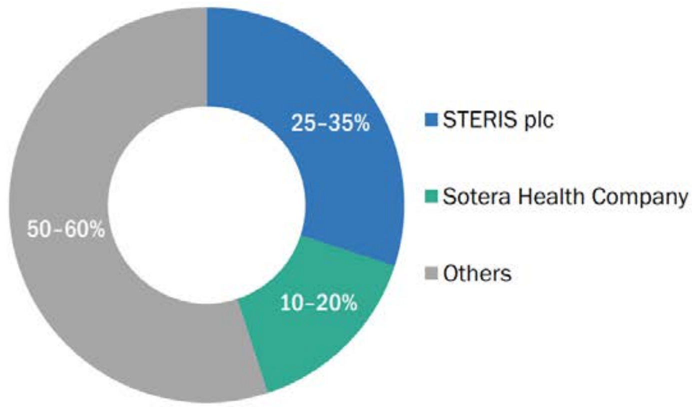
Sterilization services vendors offer a wide range of sterilization technologies and services, including equipment and contract sterilization services such as EtO sterilization, Noxilizer sterilization (NO_2), gamma sterilization, E-beam radiation sterilization, steam sterilization, X-ray irradiation, and other sterilization validation methods. Prominent players in the sterilization services market include Steris plc, Sotera Health Company, E-Beam Services, Inc., Cretex Companies, Inc. Avantti Medi Clear (Mexico), and SteriTek, Inc.[64] The Table below provides a summary of key players and associated ionization technology offerings.

Table 12: Sterilization Services of Major Vendors

Company	Ethylene Oxide	Gamma	Electron-Beam	Steam	X-Ray	Other Methods
STERIS plc	Y	Y	Y	Y	Y	Y
Sotera Health Company	Y	Y	Y	N	N	Y
E-BEAM Services, Inc.	Y	Y	Y	N	N	N
Cretex Companies, Inc.	Y	Y	Y	Y	Y	Y
Avantti Medi Clear	N	N	Y	N	N	N

Source: Reprinted with permission from MarketsandMarkets, 2023

The global sterilization services market is consolidated at the top and highly competitive, with various players governing major shares in the market. The largest players are STERIS plc and Sotera Health Company (in the following figure).



Note 1: Others include companies such as Stryker Corporation (US), Advanced Sterilization Products (ASP) (US), E-BEAM Services, Inc. (US), MMM Group (Germany), Belimed AG (Switzerland), BGS Beta-Gamma-Service GmbH & Co. KG (Germany), Medistri SA (Switzerland), Noxilizer, Inc. (US), H.W.Andersen Products Ltd. (US), Cosmed Group (US), Cretex Companies, Inc. (US), Life Science Outsourcing, Inc. (US), MICROTROL Sterilisation Services Pvt. Ltd. (India), Medline Industries, Inc. (US). Avantti Medi Clear (Mexico), Steripure SAS (France), Europlaz Technologies Limited (UK), Centerpiece (US), Midwest Sterilization Corporation (US), Blue Line Sterilization Services, LLC (US), SteriPack Group (Ireland), SteriTek, Inc. (US), and Sterilization Services (US).

Figure 12: Sterilization Services – Market Share, by Key Player, 2021

Source: Reprinted with permission from MarketsandMarkets, 2023

Brief profiles of some of the key companies in this industry are discussed in the following sections.

3.1 Avantti Medi Clear

Avantti Medi Clear (Tijuana, Mexico) specializes in medical device sterilization and offers outsourced electron-beam sterilization product testing, dosimetry, dose mapping, and dose validation studies to medical device manufacturers. It provides medical device manufacturers with an E-beam sterilization facility that will allow for local sterilization and reduce the need to ship to the U.S. for sterilization. "The building is 31,071 square feet (2,900 M2) which is sufficient space for operation and will allow for future modification and expansion. The electron beam facility instrumentation includes one 10 Mev (20 Kilowatt) vertically mounted electron beam linear accelerator, built, and engineered by Mevex. The accelerator and the conveyor system are automated and can be calibrated to deliver doses ranging from a few Grays to thousands of kilo Grays."[65]

Avantti Medi also has a dosimetry laboratory that can facilitate testing and dose mapping requirements for new products. It provides medical device manufacturers with an E-beam sterilization facility that will allow for local sterilization and reduce the need to ship to the U.S. for sterilization.[66]

3.2 E-Beam Services, Inc.

E-Beam Services, Inc. is located in Lebanon Ohio and was founded in 1985. E-BEAM Services is the largest contract electron-beam provider in the US, with greater than 500 kW of installed accelerator capacity (enough to process nearly one billion pounds of material annually). The company's portfolio of sterilization services includes medical device sterilization, pharmaceutical and controlled substance sterilization, refrigerated/cold sterilization, E-beam cold sterilization, bioreduction, and validation services. The company offers its services in the medical device, pharmaceutical, and industrial markets for sterilization and validation purposes.[67] E-Beam operates the three facilities in the U.S.,

- Lebanon, OH - 4.5 MeV, 150 kW accelerators
- Cranbury, NJ - 4.5 Mev, 150 kW accelerators
- Lafayette, IN - Lafayette, 1.5 MeV, 75 kW accelerator.[68]

Figure 13: E-Beam Services Sterilization Process

Source: Click here to see video

3.3 Cretex Companies, Inc.

Cretex (Elk River, MN) was founded in 1917 and is a group of manufacturing companies operating across medical, aerospace & defense, industrial, and infrastructure industries. It designs, manufactures, and markets medical, industrial, and commercial products and outsources end-of-line services. Cretex Companies include Cretex Medical, Cretex

Specialty Products, and Cretex Materials. It offers medical device sterilization services through its company, Cretex Medical in partnership with sterilization facilities across the country. Cretex Medical consists of Juno Pacific division, Meier, Quality Tech Services (QTS), rms Company, rms Surgical, and Spectralytics.

Founded in 2001, QTS offers a full range of services to the medical device market, including assembly, packaging and contract sterilization.[69] The company's sterilization services include contract sterilization services, ethylene oxide services, gamma irradiation services, electron-beam irradiation services, steam and other methods, sterilization validation, dose audits, bioburden testing, product sterility testing, endotoxin testing, and various other sterilization and laboratory testing services.[70] The company has 14 facilities across the U.S. located in Minnesota, California, Tennessee, and Wisconsin.

Figure 14: QTS Medical Device Outsourcing – A Cretex Medical Company

Source: Click here to see video

3.4 Steris plc

STERIS markets an array of contract processing services using gamma irradiation, electron-beam processing, and EtO technologies, along with a range of laboratory testing services. It has a strong geographic presence across North America, Latin America, Europe, Asia, and the Middle East & Africa. Steris is one of the largest providers of gamma radiation sterilization services in the United States with 14 facilities, as well as 10 ethylene oxide gas sterilization facilities and one electron-beam radiation facility. Steris has 12 gamma sterilization facilities in the United States that are located in Ontario, California; Libertyville, Illinois (three separate facilities); Northborough, Massachusetts; Whippany, New Jersey; Chester, New York; Groveport, Ohio; Vega Alta, Puerto · South Carolina; El

Paso, Texas; and Sandy, Utah. Steris has an x-ray irradiation facility for medical devices in Europe. This second European location.

Figure 15: X-Ray Sterilization Facility in Venlo, the Netherlands

Source: Click here to see video

Steris has been expanding its sterilization services capacity in the U.S. as well as globally. In December 2020, STERIS announced the expansion of its facilities in Thailand with the addition of X-rays to its existing gamma irradiation capacity. The accelerator is a 5-7 Mev – 700 kW Rhodotron with a tantalum target.[71] In October 2019, STERIS expanded the Radiation Technology Center in Libertyville, Illinois to include X-ray and electron beam technologies.[72] In 2022, STERIS announced plans for the construction of an X-ray radiation processing facility in Tullamore, Ireland.[73]

Steris' Mevex (Ottawa, Canada) subsidiary is a manufacturer and supplier of integrated sterilization equipment, with a range of equipment and services from e-beam, x-ray, ethylene oxide, conveyors, and robotics to meet customized needs. Mevex claims it has built more than 100 accelerators for leading contract sterilization companies, top medical device manufacturers and research institutes.[74] Some of the products are listed below.

Table 13: Mevex – X-Ray products

Design energy	Typical power	Variable energy	Optional dual technology (X-ray / e-beam)	Target applications
3 MeV	10 – 150 kW	Y	Y	Wire and cable polymer crosslinking Polymer crosslinking (wire, cable, tube, pipe, sheets, etc.) R&D self-shielded irradiator Alternative to Gamma Cell GC220
5 MeV	50 – 100 kW	Y	Y	X-ray for food irradiation (sanitary and phytosanitary treatment)
5 – 7,5 MeV	40 kW	Y	Y	5 MeV X-ray for food irradiation 7,5 MeV X-ray for medical devices sterilization
7,5 MeV	100 – 300 kW	Y	Y	7,5 MeV X-ray for medical devices sterilization
10 MeV	20 – 80 kW	Y	Y	10 MeV E-beam for medical devices sterilization
25 MeV	10 – 40 kW	Y	Y	Gemstone irradiation

Source: MEVEX[75]

3.5 SteriTek, Inc.

SteriTek (Fremont, CA) is a highvolume E-beam/X-ray contract sterilizer and R&D innovation center that provides on-demand sterilization, microbiology, cross-linking, and expert consultative services to the medical device, biotech, pharmaceutical and other industries.[76] The company's facility in Silicon Valley has two 10 MeV 20 kW linear accelerators, using simultaneous beam processing that allows for high-volume production. The facility in Dallas (Lewisville, TX) houses three separate lines, two E-beam/X-ray 10 MeV, 30 kW dual beam lines, and a dedicated X-ray 7 MeV, 560 kW line which together will increase the total throughput by fivefold, once in full operation.[77]

SteriTek has been expanding its sterilization services capacity in the U.S. In 2019, SteriTek added x-ray to its existing e-beam services in Fremont, California. In 2021, SteriTek announced plans to open a new 103,000-square-foot facility in Lewisville, Texas. According to SteriTek, the company "is nearly at capacity with their current facility, and this new one will give the company room to grow and further develop."[78] The Texas Dallas facility opened in April 2023. This facility houses three separate lines, two E-beam/X-ray 10 MeV, 30 KW DualBeam lines, and a dedicated X-ray 7 MeV, 560 KW line "which together will increase total throughput by fivefold."[79] In 2022, SteriTek announced plans to invest $59.9 million to build an East Coast sterilization facility in Burlington, North Carolina.[80]

3.6 Sotera Health Company

Sotera Health Company is a leading global provider of end-to-end critical sterilization solutions, lab testing, and advisory services for the healthcare industry. Sotera Health Company was incorporated in Delaware as the parent company for Sterigenics, Nordion, and Nelson Labs. The company operates through three business units, namely, Sterigenics, Nordion, and Nelson Labs. The company's sterilization business is comprised of Sterigenics and Nordion. The combination of Sterigenics, terminal sterilization business, and Nordion, Co-60 supply business, makes it the only vertically integrated global gamma sterilization provider in the sterilization industry. In 2020, Sotera Health Company acquired Iotron, a key outsourced provider of E-beam sterilization services in North America. This acquisition helped expand its electron-beam footprint and added new expertise to its Sterigenics business. Iotron has facilities in Columbia City (Indiana), Port Coquitlam (British Columbia), and Edmonton (Alberta).[81]

Figure 16: Who is Sotera Health?

Source: Click here to see video

Sterigenics provides a complete range of terminal sterilization services, primarily using the three major commercial terminal sterilization technologies, namely, gamma irradiation, EtO processing, and E-beam irradiation. The company provides gamma irradiation services at 23 facilities, EtO processing services at 17 facilities, and E-beam services at eight facilities.[82] Sotera also offers alternative modalities like X-ray irradiation services to serve customers in niche markets.

Sotera has been expanding its sterilization services capacity in the U.S. as well as globally. In 2022, Sterigenics began processing at its expanded E-beam facility located in Columbia City, Indiana. The company expects the E-beam accelerator to increase the capacity of the medical and pharmaceutical products that can be sterilized at the Columbia City facility.[83] Sotera has invested in expanding its sterilization services capacity in Europe and the U.S. In March 2021, Sterigenics expanded its EtO facility located in Rantigny, France. In 2021, Sterigenics S.A.S. expanded its ethylene oxide facility located in Rantigny, France, thereby increasing its European sterilization capacity.[84] In August 2017, it invested $17.5 million to expand its Fort Worth, Texas, sterilization facility, with the addition of a new Nordion JS10000 gamma irradiator, making it the largest sterilization facility in the company's global network.[85]

Nordion, a Sotera Health firm, specializes in providing innovative technologies and services for the healthcare industry. It is a global provider of non-thermal pasteurization solutions for the food industry. Nordion is also a provider of gamma irradiation technology that is used to eliminate bacteria, viruses, and other pathogens from a variety of food & beverage products. Nordion is a supplier of medical isotopes and gamma technologies for the detection, diagnosis, and treatment of illnesses and infections. Its products are used daily by pharmaceutical and biotechnology companies, medical device manufacturers, hospitals, clinics, and research laboratories. Nordion supplies products to more than 40 countries. It has offices and facilities in Europe, the US, and Asia. The company is ISO certified in ISO 13485, ISO 9001, and ISO 14001. Examples of irradiation equipment are:

- JS-10000 Hanging Tote Irradiator **–** this irradiator has a tote conveyor with an ability to utilize a second conveyor allowing multiple products requiring different doses to be processed.
- Parallel Row Pallet Irradiator is a solution for processing intact pallets of products, reducing material handling labor costs while maximizing output.
- GammaFIT is a low-cost, upgradable alternative to standard irradiators, and customers can select from the various configurations.[86]
- GammaBeam-127 is a flexible and affordable dry storage option, designed for low-volume gamma processing of materials with a wide range of densities and dosage needs. It is suitable for a wide range of applications and perfect for testing and research situations.[87]

4.0 Sterilization Services Customer Concerns

The medical device, pharmaceutical, food and cosmetics industries rely on radiation sterilization of products and ingredients. This is particularly the case where the product being sterilized is heat and/or moisture labile. Approximately 40 billion medical devices are sterilized by irradiation annually. Of these, 50% are sterilized by exposure to ethylene oxide (EtO) gas, 40% by gamma irradiation, 10% by electron beam irradiation and 3% by x-ray irradiation. The need for irradiation sterilization services is expected to grow to $3.36B by 2027 (CAGR for gamma – 6.6%, e-beam – 6.4% and x-ray – 5%). During this same time period, the medical device industry is expected to grow to ~$5B with a CAGR of conservative CAGR of 4.4% between 2022-2027.[88] Industry sterilization customers are concerned. The industries mentioned above are concerned by a potential lack of irradiation capacity and, more government restrictions on the use of EtO sterilizers, putting more strain on irradiation sterilization capacity. It appears that the users of irradiation sterilizing services and the providers of irradiation sterilization services would not support any loss of capacity.

E-beam and X-ray irradiation are both attractive alternatives to Co-60 based sterilizers. E-beam is considered to be a proven commodity and is well established within the medical device and food communities. New e-beam facilities will address much of the increased sterilization capacity need. Asclarified earlier, e-beam has limited penetration into products as compared to gamma rays and x-rays. This means that currently with e-beam only an individual carton can be sterilized at one time as opposed to gamma or x-ray irradiation which can sterilize pallets of product at one time. On the other hand, e-beam sterilization can be done in seconds while gamma irradiation can take up to 2.5 hours. New e-beam facilities will be designed to reincorporate boxes back onto pallets for shipping.

X-ray sterilization is as effective as gamma in terms of deep penetration of ionizing radiation into the pallet. It is faster than gamma, but not quite as fast as e-beam. Per MarketsandMarkets, now that x-ray sterilization has been demonstrated to be equivalent to gamma sterilization, more companies will be willing to go to x-ray as the sterilization source for new products. However, the medical device, pharmaceutical and food industries will be reluctant to change to a new sterilization process for their products due to regulatory hurdles that will have to be overcome before the new sterilization process can be implemented. Typically, the regulatory agency will want to review new data to ensure that the product/packaging remains the same from the old process to new.

Experience has shown that this can potentially take years and cost millions of dollars to gain this approval.

An issue that sterilization service customers will have to deal with in the next 2 to 5 years is the potential reduction in industry-wide ethylene oxide sterilization capacity. Currently in the U.S., 50% of all medical devices, or 20 billion, are sterilized by ethylene oxide (EtO) annually.[89] The Environmental Protection Agency is proposing new rules that will directly impact the operation of the 86 EtO sterilization facilities by requiring updated ETO abatement processes to be implemented. These include:

- *Reduce the maximum concentration of EtO used in sterilization cycles.*
- *Establish air pressure gradient so that air is always flowing from low-EtO concentration to high-concentration spaces.*
- *Install enclosed conveyors to automate movement of sterilized and aerated materials.*
- *Combine sterilization and aeration chambers.*
- *Additional respirator requirements for anyone handling EtO or products sterilized with EtO.*
- *Require all commercial EtO sterilizers register with and obtain Title V permits from their local permitting authority, usually their state government.*[90]

The large EtO sterilizers such as Steris and Sterigenics already have programs in place to reduce EtO residuals and emissions.[91,92] It will be the smaller, one or two location companies that will not be able to comply with the new EPA rule due to the cost to upgrade facilities and the additional regulatory burden to obtain and maintain Title V registration.[93] The impact on industry-wide EtO sterilization capacity will be an initial reduction as the smaller operations close. However, it is likely that the big players in the EtO sterilization will acquire the assets of the smaller operations, bring them up to meet the new regulations and, claim the capacity as their own.[94] EtO as a method of sterilizing medical devices cannot be replaced with currently available technology. EtO is used to sterilize items that cannot be sterilized by other means and alternate sterilization capacity is inadequate. It should be noted that besides the EtO sterilization services industry, trade organizations such as Ethylene Oxide Sterilization Association and the Advanced Medical Technology Association as well as other federal agencies including the FDA and the SBA are pushing EPA to build flexibility into their proposed rules. All recognize that EtO is critical to the nation's healthcare system.

The impact of the new EtO rule on sterilization service customers will minimally impact the demand for irradiation sterilizers. The need for regulatory registrations due to switching to a new sterilization source will be onerous with a high possibility of failure.

This is due to the fact that most products that are sterilized by EtO cannot be sterilized by other means, including radiation.[95] In a worst-case scenario, the medical device manufacturers will send their products offshore for sterilization.

Table 14: Medical Device and Pharmaceutical Hurdles and Solutions Transitioning from Gamma to X-Ray and/or E-beam Sterilization

Hurdle	Solution
Regulatory Reregistration – Time and Expense	Development of plastic master files (PMF's) by plastic resin manufacturers. PMF's contain evidence of safety and efficacy when sterilized for X-ray and Ebeam. No need for company to recreate data. Speed reregistration and minimize failure. Done in conjunction with FDA.
Lack of Capacity	Incentivize Sterilization Service Providers to build new and/or increase X-ray and Ebeam capacity. Provide reduced cost/green electricity.
Impact on Supply Chain	Incentivize new facility construction for optimal transportation location.
Cost	Accelerate the development of technology to improve X-ray output efficiency. Power consumption and cooling need reduction will be necessary for cost equivalency when compared to gamma.
Many Gamma Options	Phase out new gamma sterilization capacity. This will force the sterilization services industry to accelerate the construction more x-ray and ebeam sterilization facilities. Incentivize medical device manufacturers to validate manufacturing and sterilization of new products using x-ray or ebeam.
Reduction in EtO Sterilization Capacity	Support efforts by FDA to fund the development of zero EtO emissions technology.

Source: R. Smerbeck, SME

NNSA Response

NNSA's Office of Radiological Security (ORS) works with government, law enforcement, and businesses across the globe to protect radioactive sources used for medical, research, and commercial purposes; remove and dispose of disused radioactive sources; and reduce the global reliance on high activity radioactive sources through the promotion of viable non-radioisotopic alternative technologies. 96 The ORS is actively looking for ways to make e-beam and especially X-ray irradiation viable alternatives to Co-60 sterilization. Some efforts include:

- Programs with the FDA to ease the regulatory burden when switching sterilization methods.

- Working jointly with industry to compare the effects of gamma, e-beam and x-ray sterilization on plastics and other polymers commonly used in medical devices.
- Funding R&D efforts through SBIR and other funding programs focused on technology solutions that would make x-ray irradiation more attractive to sterilization service providers as well as sterilization service users (i.e., medical device, pharmaceutical, food and cosmetic industries).

To continue to address the hurdles above, it is recommended that ORS should strengthen relationships within the sterilization services industry and forge new relationships within the industries that rely on gamma sterilization. The goal here would be to identify the proper incentives to overcome any hurdle they may have to moving from gamma sterilization to x-ray and e-beam sterilization.

5.0 Industrial Radiography

In this section, the use of Co-60 in neutron radiography is explored, as well as alternatives. Radiographic testing is a technique for volumetric non-destructive testing (NDT) and is often used to reveal internal, surface, and sub-surface irregularities. This technique is widely used in aerospace, power generation, construction, petroleum, chemical and automotive industries, and for all types of components and parts. The technique is commonly used on welded parts, ferrous and non-ferrous castings, forgings, composites and is also used for corrosion mapping and the measurement of wall thickness. Nearly all gamma-radiography is done with either Co-60 or iridium-192 sources. There are a few other radioactive isotopes suitable for gamma-radiography that are used in special applications.[97] Radiographic nondestructive evaluation can be used in stationary and mobile configurations, depending on the application.

The following gamma sources are used in industrial radiography applications: Cobalt-60, Cesium-137, Iridium-192, Americium-241 and Selenium-75.[98] Iridium-192 is used in industrial nondestructive testing to image the interior or metal castings, manufactured components and welds. According to the National Academies "there are approximately 4,000 Category-1 and Category-2 iridium-192 sources used in NDT which accounts for approximately 5 percent of all Category 1 and Category 2 sources in the United States."[99] Although cobalt-60 is almost always installed in stationary applications, iridium-192 is most frequently used in mobile applications and frequently requires replacement due to the short half-life (74 days). This makes them most vulnerable to misplacement or loss.[100]

Categories 1 and 2 materials are currently subject to enhanced security measures and tracked by the Nuclear Regulatory Commission (NRC).

Tracking technologies have focused on the most vulnerable sources. ORS has sponsored the development of the **Mobile Source Transit Security (MSTS)** for tracking industrial radiography and well logging sources.[101] MSTS uses secure satellite and cellular communication networks for tracking. Spent or disused sources can be returned to the manufacturer or supplier and often replaced by a new source. However, this process is often challenging, as one needs to provide documentation on the country of origin for the source and where manufacturing occurred. Another challenge is the limited availability of certified transportation containers and the forms that need to accompany them.[102]

Figure 17: NNSA's ORS Mobile Source Transit Security (MSTS) System

Source: Click here to see video

The following discussion provides an introduction to the processes that are currently used in various industrial radiological applications.

5.1 Industrial Radiography Market

Industrial radiography is commonly used in the petrochemical and gas, construction, automotive and transportation, and manufacturing are a few examples of where industrial radiography is commonly used. Some common applications of industrial radiography are:

1. Inspecting the welds of pipelines and pressure vessels in the petrochemicals and gas industry

Figure 18: Real-Time Radiography (RDR) for Pipeline Weld Inspection
Source: click here to see video

2. Monitoring and regulating equipment according to standard values at manufacturing plants in the mining industry, metal industry, and pipe and tube manufacturing.

Figure 19: Cesium 137 Source Lost and Found in Western Australia
Source: Click here to see video

3. Inspecting the integrity of rebar reinforcements during building construction to ensure they are continuous and intact.[103]

The worldwide market for industrial radiography was approximately $532 M in 2020 with a compound annual growth rate (CAGR) of 8.1%, increasing to $784 M by 2025. In 2019, North America, which includes Canada, the U.S. and accounted for the largest share of ~62.5% of the overall industrial radiography market, followed by the European market. The dominance of the North American market is attributed to the use of radiography in nondestructive testing in manufacturing, mining, aerospace, power generation, petrochemical & gas, and automotive and transportation industries.

Table 14: Global Industrial Radiography Testing Market, By Region, 2018-2025 (USD Million)

Region	2018	2019	2020	2021	2023	2025	CAGR (2020-2025)
North America	150	161	173	185	211	242	7.0%
Europe	121	131	141	152	177	205	7.8%
APAC	114	124	136	149	178	212	9.3%
RoW	69	76	82	90	106	126	8.8%
Total	**455**	**492**	**532**	**575**	**672**	**784**	**8.1%**

Source: Reprinted with permission from MarketsandMarkets

The following table provides a forecast by end user. The Automotive & Transportation, Aerospace and Petrochemicals & Gas industries are the largest users globally of gamma radiography.[104]

Table 15: Global Industrial Radiography Testing Market, By End User, 2018-2025 (USD Million)

End User	2018	2019	2020	2021	2023	2025	CAGR (2020–2025)
Petrochemicals & Gas	95	104	114	125	149	177	9.2%
Power Generation	79	86	92	100	116	134	7.7%
Manufacturing	62	66	72	77	89	103	7.6%
Aerospace	99	107	116	125	147	172	8.2%
Automotive & Transportation	103	111	119	128	148	171	7.5%
Others	16	17	19	20	23	26	7.3%
Total	**455**	**492**	**532**	**575**	**672**	**784**	**8.1%**

Note: Other end users include pulp and paper, plastic and polymer, and research and development.

Source: Reprinted with permission from MarketsandMarkets

MarketsandMarkets predicts market growth (CAGR 8.1% between 2020-2025). The drivers for market growth include:

1. Global demand for consumer electronics requiring additional quality testing.
2. Rapid technological advancements driving an increased manufacturer focus on research and development.
3. Increased demand for NDT and inspection services from power generation industry.
4. Technological advancements in NDT and inspection techniques and emergence of new applications.
5. Importance of NDT and inspection activities in controlling corrosion in aging infrastructures.[105]

5.2 Alternative Technologies for Industrial Radiography

Alternatives to Co-60 were discussed in two government reports (1) a 2019 Department of Homeland Security's Cybersecurity and Infrastructure Security Agency report titled, "Non-Radioisotope Alternative Technologies White Paper,"[106] and (2) 2021 Government Accountability report titled, "Alternatives to Radioactive Materials: A National Strategy to Support Alternative Technologies May Reduce Risks of a Dirty Bomb." The GAO report noted that, "users of applications that employ high-risk radioactive materials identified six factors they take into account when determining whether to adopt alternative technologies including: technical viability of alternatives, device cost, costs to convert (such as facility renovations), disposal of radioactive materials, regulatory requirements, and liability and other potential costs associated with possessing high-risk radioactive materials."[107]

X-Ray and Ultrasound testing were considered to "have limitations that hamper their ability to replace radioactive materials in most applications (e.g., need for external power supply)." In discussion with users and evaluation of technical reports, the Government Accountability Office found that "these alternatives have not yet shown sufficient technical viability to supplant the use of devices using high-risk radioactive materials." Specifically, the short comings of X-ray systems require external 220V power supplies and water cooling, which make them difficult to operate in the restricted spaces, harsh environments, or remote locations where industrial radiographers typically work.

5.2.1 X-ray Radiography with Industrial Radiography

In a number of instances, gamma radiography has been replaced by Microfocus X-Ray systems in factories by benchtop and shop-floor X-ray systems. Microfocus X-ray inspection is a 3D NDI technique that allows the testing and 3D analysis of various materials in a non-destructive manner. It is used in a wide range of industries, including the electronics, automotive, semiconductors, and aerospace industries. These systems are available from several global manufacturers such as Waygate Technologies/Baker Hughes, Shimadzu and Hamamatsu Photonics. Below is an example of a microfocal X-Ray system from Shimadzu. Xslicer SMX-6010 is research only planer X-ray inspection system, featuring a micro-focus X-ray generator and a 3-megapixel flat panel detector. However, they are quite large and not suitable for all field locations.

Figure 20: Xslicer SMX-6010
Source: Shimadzu[108]

Portable and semi-portable X-Ray generators are not suitable for all field locations since they are large and need external power. Below is an example of a semi portable X-ray generator from Waygate Technologies, the Seifert ERESCO MF4 Portable Industrial X-ray Generator.

Figure 21: Seifert ERESCO MF4 Portable Industrial X-ray Generator
Source: Waygate Technologies[109]

X-Ray Crawlers – pipeline crawlers used on new or empty pipelines. They are designed to inspect circumferential butt welds in new pipelines, such as oil and gas transmission pipelines. For example, the CR2 Pipeline Crawler X-Ray System from JME is described as "exceptionally compact, lightweight, and deployable in an Internal Diameter range between 5.5-18 in (140 mm-457 mm). Coupled with X-ray generators from JME or ICM, this system can produce internal panoramic single-wall-single-image radiographs of very high quality."[110]

Figure 22: CR2 Pipeline Crawler X-Ray System
Source: JME[111]

X-ray radiography is currently the main non-source-based alternative technology used in industrial radiography. There are many instruments available from several vendors, used alongside neutron radiography. A study conducted by Sandia for the NNSA ORS in 2021 showed that most NDE providers own a mix of gamma ray and x-ray-based devices. However, the customers are the ultimate decision makers with respect to the choice of equipment to be used in specific applications based on factors such as cost and performance requirements. The Sandia study concluded that it is unlikely that x-ray-based devices would completely replace currently existing radioactive source-based industrial radiography devices in the near future.[112] However, breakthroughs in power consumption and cooling could remove industries' primary qualms with x-ray radiography as a replacement for gamma radiography.

5.2.2 Other Techniques

Other nondestructive methods exist, such as (1) ultrasonic testing, (2) visual testing (VT), (3) magnetic particle testing (MPT), (4) liquid penetrant testing (LPT), (5) Eddy-current testing (ECT), (6) acoustic emission testing (AET), and (7) others in development. Acoustic emission and ultrasonic testing (UT) that can be used in lieu of industrial radiography. However, Ultrasound imaging has shortcomings, such as unable to work if sonic couplant fluid freezes.[113]

Figure 23: Robotic Weld Radiography

Source: Click here to see video

In terms of market size, the ultrasonic testing (UT) technique accounted for a share of ~32.6% of the nondestructive testing and inspection market in 2022. It is projected to grow at a CAGR of 8.0% from 2023 to 2028. In 2022, the UT technique segment accounted for the largest share of ~32.6% of the market. UT has evolved considerably over the last few decades making it an important tool for identifying and quantifying surface and subsurface defects.

Table 16: Global NDT Testing and Inspection Market, by Technique, 2023-2028 (USD Million)

Technique	2023	2024	2025	2026	2027	2028	CAGR (2023-2028)
UT	827	893	968	1,046	1,128	1,213	8.0%
RT	571	614	662	710	758	807	7.1%
VT	402	429	460	492	525	559	6.8%
ECT	384	418	460	504	548	594	9.1%
MPT	179	191	205	219	232	246	6.5%
AET	79	83	86	90	93	96	3.9%
LPT	35	38	40	42	44	46	5.2%
Others	53	59	65	73	82	93	12.0%
Total	**2,530**	**2,726**	**2,947**	**3,175**	**3,410**	**3,653**	**7.6%**

Source: Reproduced with permission from MarketsandMarkets, August 2022

5.3 Domestic Manufacturers of Gamma Radiography Instruments

An open-source literature was performed to identify manufacturers of gamma radiography instruments. They are available from very few vendors, discussed below.

5.3.1 QSA Global, Inc.

QSA Global, Inc. is a division of Illinois Tool Works a fortune 200 company. QSA manufactures and distribute radioisotope products globally via over 30 international distributors and trading partners. QSA has remained a premier supplier of high energy radiation source products, technologies, and services since the 1940s and is a leading manufacturer of Am-241, AmBe, Cf-252, Cs-137, and Co-60 for the oil well logging, industrial gauging & analysis, and nuclear industries, and a supplier of Ir-192, Se-75, and Co-60 sealed radioisotope sources to the industrial gamma radiography industry.

QSA markets the SENTINEL SENTRY Series gamma-ray source projectors, shown below.

Figure 24: SENTINEL™ SENTRY Series Co-60 Gamma-Ray Source Projector
Source: QSA[114]

Below are the SENTRY mobile industrial radiography.

QSA Global, Inc. Sentinel 880 Delta Source Projectors from QSA have Cobalt-16. According to QSA, “With over 12,000 in service worldwide from Alaska’s North Slope to harsh Middle East desert environments, the SENTINEL 880 Series has two decades of proven reliability and durability.”[115]

SENTINEL 880 Series Delta

The most preferred gamma-ray source projector on the market.

Ir-192	150 Ci (5.55 TBq)
Se-75	150 Ci (5.55 TBq)
Yb-169	108 Ci (4.00 TBq)
Weight	52 lb (23.6 kg)
Transport	Type B(U) package

SENTINEL 880 Series Elite

Ideal for use with low-energy isotopes and lower Ir-192 activity.

Ir-192	50 Ci (1.85 TBq)
Se-75	150 Ci (5.55 TBq)
Yb-169	108 Ci (4.00 TBq)
Weight	42 lb (19.0 kg)
Transport	Type B(U) package

SENTINEL 880 Series Omega

Best suited for offshore applications and countries with strict regulations.

Ir-192	15 Ci (0.55 TBq)
Se-75	80 Ci (3.00 TBq)
Yb-169	108 Ci (4.00 TBq)
Weight	33 lb (15.0 kg)
Transport	Type A package

Figure 25: SENTINEL 880 Series Gamma-Ray Source Projectors

Source: QSA[116]

QSA Global also markets the Co-60 sealed radioisotope sources to the industrial gamma radiography industry. QSA Global, Inc.'s Co-60 sealed sources are used to perform industrial gamma radiography with relatively short exposure time on thicker materials such as heavy castings, thick steel weldments, and concrete.

Table 15: Co-60 in Gamma Radiography

Gamma Energy Range	1.17-1.33 MeV
Steel Thickness	2.0–6.0 in (50-150 mm)
Concrete Thickness	10 to 40 in (200-1,000 mm)
Light Alloys Thickness	1.5–7.5 in (40-190 mm)
Radioisotope Output	At 1 m per Ci (37 GBq): 1.30 R/hr (13.0 mSv/hr) At 1 ft per Ci (37 GBq): 14.0 R/hr (140 mSv/hr)
Half-Life	5.27 years
Special Form Certification	USA/0377/S-96

Material	Approximate Material Density	Approximate Half-Value Thickness
Concrete	2.35 g/cm^3	2.400 in (61.0 mm)
Steel	7.80 g/cm^3	0.827 in (21.0 mm)
Lead	11.34 g/cm^3	0.500 in (12.7 mm)
Tungsten	17.80 g/cm^3	0.310 in (7.9 mm)
Depleted Uranium (DU)	18.70 g/cm^3	0.270 in (6.8 mm)

Source: QSA Global[117]

5.3.2 Source Production & Equipment Co.

Source Production & Equipment Co. (St. Rose, Louisiana) markets the SPEC-300, shown below. The SPEC-300 is a mobile (Class M), Category II (ISO3999), Type 1 (ANSI N432), depleted uranium shielded Cobalt 60 exposure device used for industrial gamma radiography nondestructive testing applications. The SPEC-300 system consists of the SPEC-300 exposure device (camera), a model G-70 source assembly and associated equipment. The SPEC-300 exposure device is intended for industrial gamma radiography operations at temporary job site and permanent facilities in all industries and locations. Typical industries and locations are associated with oilfield, petrochemical, marine, construction, manufacturing, and aerospace activities. It is expected that the equipment will be used at offshore structures, metal fabrication yards, foundries, chemical plants, refineries, shipyards, building sites, laboratories, and maintenance facilities.[118]

COMPLETE SYSTEM INCLUDES:

	Description	QTY	Part No.
A	SPEC-300 Device with Cart	1	190600-3
B	35ft (10.7m) Rigid/Flex Control	1	257236
C	7ft (2.1m) Guide Tubes	2	229207
D	Quick Disconnect	1	190789-1
E	Source Stop	1	222530-1
F	Coupling (guide tube connection)	1	213004-1
G	5HVL Collimator (tungsten)	1	231019-1

ADDITIONAL OPTIONS:

- Custom length guide tubes - up to 21ft (6.4m)
- 50ft (15.2m) flex/flex controls
- Tungsten collimators :
  - 5.5 HVL end port
  - 7HVL 360° or sideport
  - 16HVL Side port
  - custom request
- Tool kits
- Replacement components

Figure 26: SPEC-300

Source: Source Production & Equipment[119]

According to a 2020 presentation by QSA, there are more than 10,000 radiography sources sold globally per year, with about 4,000 of those sold into the U.S. market. There are more than 1,000 licensees of radiography cameras in the United States.[120] Below is an example of a mobile neutron radiography equipment.

SENTINEL SENTRY Series 330

Co-60	330 Ci (12 TBq)
Weight	780 lb (354 kg)
Weight of DU Shield	485 lb (218 kg)
Transport	Type B(U) package

SENTINEL SENTRY Series 110

Co-60	110 Ci (4.07 TBq)
Weight	605 lb (274 kg)
Weight of DU Shield	295 lb (133 kg)
Transport	Type B(U) package

Figure 27: SENTINEL™ SENTRY Series Co-60 Gamma-Ray Source Projectors
Source: QSA[121]

Industrial NDT systems are often deployed in outdoor environments.[122] For example, Cobalt-60 radiography “cameras” are used for the non-destructive inspection of welds, pipes, austenitic materials, and others.[123] Hence, gamma ray devices are preferred for such conditions for their rugged design and mobility.[124] This introduces a security concern, as devices containing radioactive material are transported and stored in vehicles while not in use, presenting a risk of theft. [125]

5.4 Potential Opportunities for X-ray Technologies in Industrial Radiography

The following is a short list of areas where X-ray systems designed for industrial radiography applications could make an impact. Much of the inspiration for these ideas comes from a Danish company called Comet X-ray that has developed a series of X-ray mobile devices. The pipeline inspection case study using Comet’s mobile X-ray technology in combination with Shaw Pipeline Inspection Services speaks to new possibilities.

- Focus on ruggedizing x-ray systems so that they can be used in the field.

- Develop pulsed X-ray systems that can be run on battery power. This could eliminate the need for generators in the field. Also, pulsed X-ray systems may need less cooling, making them more suitable for field applications.

6.0 Summary and Conclusions

As noted at the outset, the Office of Radiological Security (ORS) within the Department of Energy's National Nuclear Security Administration is charged with encouraging voluntary protection of radiation sources and the promotion of non-radioisotopic alternatives. As noted in this report the use of cobalt-60 as a sterilization agent plays a critical role in medical device, pharmaceutical and food safety. In the area of non-destructive testing, it is critical for flaw detection in aircraft structures and engines parts. Radiation sources allow for the inspection of oil and gas lines for early identification of potential structural failure. Alternative technologies that can replace radiation sources have or are being developed.

With regard to radiation sterilization, the NNSA is promoting replacing Co-60 based gamma sterilization with x-ray or electron beam sterilization. Both technologies are already commercially operational. They both are radiation sterilization sources. The difference is that they are only "on" when power is supplied to the beam generators. By contrast, gamma sterilizers are always on since they always emit gamma rays due to radioactive decay.

The factors that continue to limit conversion from Co-60 to x-ray or e-beam are:

- Lack of capacity,
- cost prohibitive changes required by regulatory agencies to reestablish product safety and efficacy when switching to a new sterilization method,
- disruption of currently established supply chains,

- the need for more gamma sterilization capacity to replace the expected reduction of allowable Ethylene Oxide sterilization facilities,
- the increased cost of electricity

Technologies that could make transitioning to x-ray and ebeam sterilization more feasible would be those that can reduce the amount of electricity needed to generate radiation beams and improving the efficiency of the linac and/or the x-ray generator. These benefits could allow for smaller, and/or off – grid facilities to be constructed. As high gamma sterilizers are located throughout the world, their replacement is an issue, not only in the United States, but globally.

In the field of non-destructive evaluation (NDE), industrial radiography utilizes high energy gamma radiation sources to reveal internal defects and flaws that could impact the reliability of metal parts for the aeronautical, automobile and petroleum industries (as well as any other industry where NDE methods are required). The gamma rays penetrate through the part in question and impinge on a film or digital imaging plate. Examination of the image reveals the flaw in question. X-ray radiography is being evaluated as a suitable replacement for gamma radiography. There are marketed x-ray radiography systems that have the capability of replacing gamma radiography systems. However, they are not accepted readily since they are relatively new to the industry and their high-power requirements make them unsuitable for field use. Once again x-ray sources that require less electrical power would be of value – particularly if they could be powered by commercially available portable gen sets.

The radiation sterilization services, and radiation sterilization device industries are dominated globally by a few players, notably Soltera, Steris IBA and Ebeam Tech. All have a presence in x-ray sterilization, e-beam sterilization, or both. The use of e-beam and x-ray sterilization will increase, particularly to take up any slack due to the anticipated loss of ethylene oxide sterilization capacity. Companies such as these could be supportive of technological advances from small business and high energy physics laboratories.

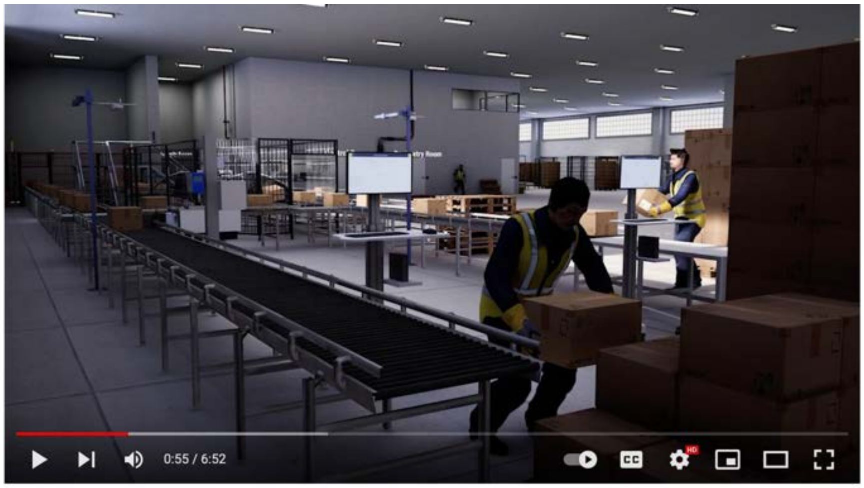


Figure 28: Visit the e-beam and Irradiation Center Called be Flex
Source: Click here to see video

Production level sterilization facilities based on e-beam and x-ray irradiation exist. NDE using x-rays has been proven to perform equally with gamma sources. New technology may accelerate the construction of new facilities and x-radiography use. However, in the near term, it will likely require financial incentives to both the sterilization service providers and their customers as well as the users of gamma radiography for NDE purposes to diminish their use of gamma sources.

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