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MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Gamma Irradiation: A Sustainable Future for Medical Device Sterilization

Why gamma remains a green choice for medical device sterilization.

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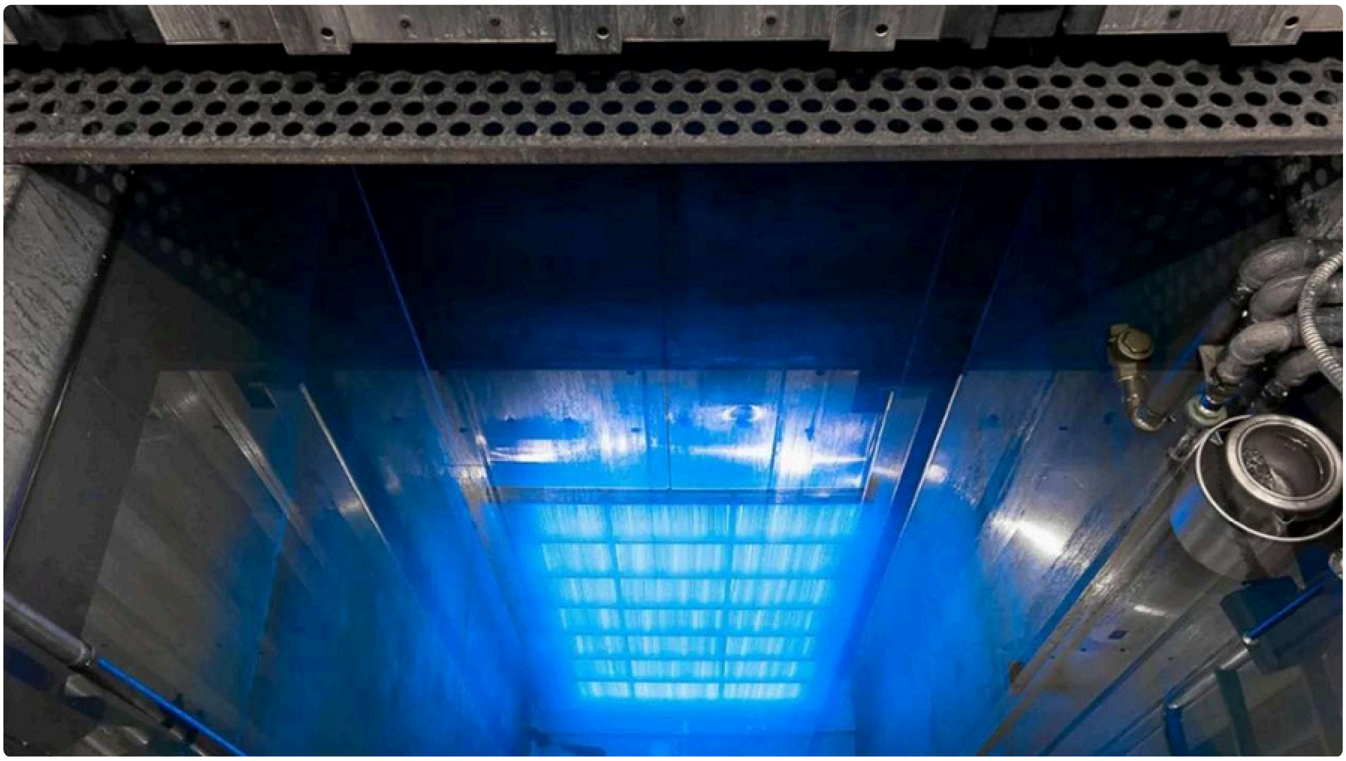

Cobalt-60 sealed sources located inside a rack within the storage pool of a gamma irradiator. IMAGE COURTESY OF NORDION INC.

The use of gamma irradiation technology for the sterilization of medical devices was established in the 1950s and its application grew rapidly over the following decades along with the increased use of single-use devices.

Today, roughly 300 commercial scale gamma irradiators operate globally with an estimate of 80% of their capacity used for sterilization. This is equivalent to about one third of single-use devices, or ~25B individual items, sterilized with gamma irradiation every year. Therefore, a patient in surgery or receiving wound care or simply having a blood sample taken, is highly likely to be treated with products that have been sterilized with gamma irradiation.

Demand for gamma irradiation continues to grow due to the increased healthcare needs of a growing and aging population, the development of new healthcare technologies, and improved access to healthcare in developing economies.

This article discusses the sustainability of gamma irradiation as demand for the technology continues to grow. It looks at sustainability in both the business and environmental definition, so: the long-term ability of gamma irradiation to meet the increasing demand as a sustainable business; and the impact of gamma irradiation on the planet as expectations of environmental sustainability and for sustainable operating practices remain important.

Business sustainability of gamma irradiation for sterilization

The gamma irradiation infrastructure is well established with many sterilization service providers, medical device manufacturers, and investors operating irradiation facilities in ~50 countries worldwide. The technology and processes are well understood, and regulators worldwide have approved its use for sterilization of a vast number and range of products. Gamma irradiation is particularly suited for bulk sterilization and is a relatively simple process when compared with other sterilization modalities. For these reasons, gamma irradiation has been widely adopted and has the basis for future growth.

However, between 2018 and 2024, growth of gamma irradiation slowed due to supply chain issues. This related to the supply of cobalt-60, the radioactive material that produces gamma radiation and is, effectively, the fuel of gamma irradiators. Like all radioactive material, cobalt-60 decays so it is necessary to top up cobalt-60 levels periodically to compensate for this decay and maintain sterilization volumes. If demand for sterilization increases, then extra cobalt-60 in addition to that compensating for decay, must also be installed to enable increased volumes to be irradiated.

Cobalt-60 is produced in 20 nuclear reactors, almost exclusively operated for electricity production, and up until 2018 there was a supply surplus. These reactors are in Argentina, Canada, China, India and Russia. Between 2018 and 2024 there were a few factors that resulted in a tightness of cobalt-60 supply which led to some processing restrictions or increased lead times for medical device sterilization. This was of significant concern to the healthcare industry during that period.

The primary contributing factor was the closure, either permanent or temporary, of several reactors during a period of high demand for sterilization. Nuclear reactors have an operational life after which they either close permanently or undergo refurbishment to extend their operation and cobalt-60 production by an additional 25-30 years. Several reactors in Canada and Argentina entered refurbishment programs, while other reactors in Russia closed permanently and experienced distribution disruptions, therefore reducing supply. This occurred at a time when demand growth had doubled compared to previous recent levels due to the Covid-19 pandemic.

Some reactor refurbishments are now complete, and others are ongoing with the programs reported as being either on time or ahead of schedule. The two major refurbishment programs in Canada will be completed in 2026 and 2033 with some of the existing cobalt-60 production reactors already back in operation. A benefit of the refurbishment program is that reactors of a certain type that do not produce cobalt-60, can be modified to enable new cobalt-60 production, as is happening during one of the refurbishment programs.

Increased cobalt-60 production and availability is already having a positive effect and demand growth has moderated from the recent historic highs. This has meant that Ottawa, Ontario-based Nordion, the world's largest supplier of cobalt-60 for sterilization, has reported that it was able to meet all demand in 2024.

For the longer-term future, Nordion is working with Westinghouse, a nuclear reactor operator, to start production of additional cobalt-60 in the world's most used reactor type. This new production will be highly scalable as there are over 300 reactors of this type in operation. Production arrangements are well progressed, and supply is anticipated to come online as soon as 2029.

It should be noted that reactor operators in Russia have also opened new cobalt-60 production reactors, although geopolitical factors make distribution of this cobalt-60 challenging. Additionally, production in India is reported as increasing, the reactor in Argentina is back to full production after recent refurbishment, and Chinese production continues reliably.

There is no doubt that the temporary period of tightness in cobalt-60 supply knocked confidence in gamma irradiation and drove some operators to invest or consider transferring product to alternative sterilization technologies. The main benefactor of this investment has been electron beam and X-ray irradiation technology. The industry has already seen these alternative irradiation modalities gain market share although demand for gamma irradiation is likely to continue growing as the market size increases and confidence in the cobalt-60 supply chain is fully restored.

The return of reactors post-refurbishment, the modification of existing reactor types to enable cobalt-60 production, and investment in new cobalt-60 production reactor technologies, positions the industry well to continue meeting demand for sterilization.

Environmental sustainability of gamma irradiation for sterilization

Environmental sustainability, minimising contribution to global emissions and reducing environmental impact, remains a focus of many businesses. The healthcare industry and their suppliers of services such as sterilization, have adopted sustainability strategies and embraced sustainable operating practices.

Adoption of sustainable practice by medical device manufacturers is complex because consideration must be given to the environmental impact of the total product life cycle. This will include considerations related to raw material extraction and processing, manufacturing, distribution, use, and the end-of-life handling of any device. This life cycle will include internal and external stakeholders, and participants in the upstream and downstream supply chain.

The sterilization step only forms a very small part of the total life cycle of medical devices, typically taken after manufacturing and packaging, and before distribution of the device. However, each operator will have their own sustainability considerations, stakeholders and supply chain to examine.

With this in mind, the gamma irradiation industry benefits from both inherent and newly adopted processes that enable it to operate with heightened sustainability credentials. This may surprise some readers because of to the use of radioactive material in this sterilization modality. The following highlights some of the steps of the gamma irradiation process.

Raw material: the majority of cobalt raw material is extracted as a byproduct of existing copper or nickel mines and is primarily used in the production of electric vehicle batteries and high-performance alloys. Only a tiny proportion ($<3 \times 10^{-6}$%) of the mined cobalt raw material is used for production of cobalt-60 in nuclear reactors.

Cobalt-60 production: cobalt raw material is prepared and inserted into certain nuclear reactors to produce radioactive cobalt-60. The primary purpose of these nuclear reactors is to produce electricity. Cobalt-60 production is a byproduct of this primary purpose and the reactors would operate to produce electricity even if the cobalt-60 was not produced. Therefore, production of the cobalt-60 has a negligible additional environmental impact on reactor operations. Additionally, of course, nuclear reactors are a clean alternative to electricity generation that produce greenhouse gases through the use of fossil fuels such as coal and natural gas.

Distribution: the shipment of cobalt-60 to operators of gamma irradiators is considered to have the largest environmental impact within the supply process. Whilst efforts are made to ship in the most efficient way, it is undeniable that transport is one of the largest sources of greenhouse gas emissions. A typical annual cobalt-60 replenishment shipment to an irradiator will fit into a single twenty-foot shipping container and, arguably, the small environmental impact of this transport can be amortised over the typically 20 year working life of the cobalt-60. Meanwhile, the transport industries have multiple initiatives to reduce their environmental impact and these will come to fruition in due course.

Irradiator operation: as we have learned, gamma irradiators sterilize medical devices using radiation from cobalt-60. This is highly beneficial because no additional electricity is required to produce this radiation for the 20-year life of the cobalt-60. Of course, the use of electricity is necessary for product handling, heating, refrigeration etc., and there are many other considerations such as material usage and waste management, but these are the same as for any sterilization modality. A significant consideration for any manufacturer or sterilization service provider is the environmental impact of transport of medical devices to and from the sterilization facility.

End of life handling: leaving the end-of-life handling of the medical device aside, as this is not within the scope of sterilization, consideration needs to be given to end-of-life handling of cobalt-60 after its 20-year working life. Nordion reports that more than 99% of cobalt-60 returned to it from the market is now recycled into new usable product.

The use of gamma irradiation clearly has a low environmental impact relative to its sterilization capacity and when compared to alternative technologies. One analysis that makes a comparison with the use of X-ray, the modality considered most equivalent to gamma for sterilization, reports that gamma produces 12 times less greenhouse gas and uses 15 times less electrical consumption than X-ray. Of course, the X-ray industry is taking steps to improve the efficiency and electrical consumption of its equipment and has also created business models that reduce the environmental impact of its operations.

Gamma irradiation for the sterilization of medical devices is sustainable for the long term in both the business and environmental definition. Increased capacity has resulted from investment is nuclear reactors that fuel the process. This will enable the industry to meet the growing demand for sterilization that results from population, economic and technology factors.Gamma irradiation is well placed to meet the sustainability demands of the medical device industry and shows some advantages over other sterilization modalities. Sustainability was a key theme at the International Meeting on Radiation Processing held in November 2024. This theme reflected the adoption of sustainable practices by the irradiation industry and a willingness to share and learn developments than will continue to reduce the environmental impact of sterilization operations.