447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 592 3400 ext. 2041
Fax: +1 613 591 7449
www.gipalliance.net

Gamma Safe. Secure. Vital.

GIPA
Gamma Industry Processing Alliance

COMPARISON OF COBALT-60 AND X-RAY TECHNOLOGIES

GIPA FACT SHEET

OVERVIEW OF COBALT-60 SEALED SOURCE GAMMA TECHNOLOGY APPLICATION

Cobalt-60 is an intentionally produced radioisotope product manufactured specifically for multiple industrial and medical applications. The largest use of Cobalt-60 is for sterilization of single use sterile disposable medical devices and products. The worldwide installed base of Cobalt-60 is approximately 290 million curies, contained in some 170 Cobalt-60 commercial gamma irradiator facilities. The United States accounts for almost one third of these facilities, and more than half of the global installed base of cobalt-60. Medical device sterilization accounts for approximately 80% of the volume of product commercially processed with gamma radiation from Cobalt-60.

The U.S. market for single use sterile disposable medical devices and products, such as syringes, catheters, surgical gloves, bandages, drapes, gowns and hundred of others, will reach an estimated $79 billion by 2007. More than 40% of these products, equating to 200 million cubic feet per year in the United States alone, are sterilized by gamma irradiation from Cobalt-60.

In addition to sterilizing medical devices, Cobalt-60 is also used to treat other product such as cosmetics, food packaging and some food products such as fruits, spices and ground beef.

PROFILE OF COBALT-60 SEALED SOURCE GAMMA TECHNOLOGY USE IN MEDICAL DEVICE STERILIZATION

a) Existing Infrastructure in Cobalt-60 Gamma Sterilization

Within the United States alone there are 51 Cobalt-60 commercial gamma irradiator facilities containing approximately 150 MCi of Cobalt-60. These facilities are owned and operated by medical device manufacturers, who use them on their manufacturing sites, as well as many contract gamma irradiation facilities, which primarily service the medical device industry.

This breadth of irradiation infrastructure, which has been built up over almost 50 years, was driven by the confidence in the technology for providing reliable and cost effective terminal sterilization for medical devices.

Each facility includes a large shielding structure in which the sterilization process is carried out together with an associated product staging and storage area specifically designed to operate with the design of an installed Cobalt-60 gamma irradiator. Regardless of the actual model of Cobalt-60 gamma irradiator, the ease of movement of product from one facility to another has been well established by both industry and regulators. This allows the medical device industry to have a large base of highly reliable service providers to ensure no interruption in sterilization capability.

A network of Cobalt-60 commercial gamma irradiator facilities has been established around the world capable of providing radiation sterilization services. This capability facilitates the movement of the Cobalt-60 gamma sterilization process thus allowing the medical device industry to select the most cost effective geography for medical product manufacturing and distribution. This ease of movement and breadth of infrastructure is a key to the medical device manufacturer being able to manage the ever-increasing cost of delivering these devices and is one aspect that allows the industry to keep overall costs down.

b) Long Term Stability and Confidence in Application for Cobalt-60 Sealed Source Gamma Sterilization

i) Regulatory Confidence in the Technology

For almost fifty years, gamma sterilization has been the technology of choice for healthcare companies who have chosen to use radiation sterilization. Medical device manufacturers and gamma technology suppliers have worked with regulatory bodies to ensure that gamma technology remains one of the safest industries in the world for both product sterilization, and transport of radiation sources. Security of supply, security of Cobalt-60 source transport and security of Cobalt-60 commercial gamma irradiators have always been of paramount importance to the Cobalt-60 gamma industry. Life-cycle source tracking is also in place with Cobalt-60 suppliers to ensure the location and disposition of all sources on an ongoing basis.

ii) Simplicity of System Design and Proven Reliability

The design of Cobalt-60 commercial gamma irradiators worldwide has been based on simple proven and tested principles, resulting in an unparalleled reliability and safety record. When x-ray and gamma technologies are compared, it is important to clarify the assumptions. On average, Cobalt-60 commercial gamma irradiators achieve upwards of 95% operational reliability. This has been proven through many years of actual operations in multiple types of facility designs. The 95% reliability is largely attributed to the predicable decay (and hence energy output) of Cobalt-60 and the relative simplicity of the product transport systems installed in commercial gamma irradiators.

The complex design of x-ray systems means that there are more potential electrical and/or mechanical problems associated with this technology. The limited availability of specialist x-ray system replacement parts and system complexity tends to make maintenance issue more protracted and means that longer times are required to effect repairs and return these machines to operation. Typical accelerator based irradiation systems in operation have shown upwards of 80% reliability in limited operations, although some experience in the industry has shown that the uptime may be less than 75% for designs that convert electrons to x-rays. These factors impact on the economics of the technology which is an increasingly critical concern due to the current trend towards "just in time" manufacture of medical products and the intolerance for unplanned and/or extended outages. In the economic analysis provided later in this document Appendix A, a factor of 95% reliability has also been assumed for x-ray facilities. However, this figure should be considered as not truly representative due to the complexity of the x-ray systems and the relative infancy of the technology in commercial sized operations. The reliability of these systems under continuous operation has not been credibly demonstrated.

c) Conversion to X-Ray

i) Implications for Device Design and Cost of Manufacture

Cobalt-60 gamma technology is currently being used to sterilize approximately 40% of all the single use sterile disposable medical devices manufactured in the United States. At this time, there are no medical products being sterilized using x-rays in the United States. The validation of this process requires extensive product material compatibility analysis, including the current and long-term impact on structural and mechanical properties. Any regulated or prescribed change to an alternate sterilization modality such as x-ray will create a significant cost to medical device manufacturers in the areas of device performance related to potential material changes and associated regulatory submissions.

The cost and time related to these changes would vary depending on the medical device selected; however, it would likely be in the hundreds of thousands of dollars for each device impacted and exceed one year of elapsed time for all associated work and approvals.

In a situation where a change of this nature was not driven by product or market need, many manufacturers may select to not incur the added cost and liability of device change and select an alternate resolution. This may result in device manufacturers moving off shore where gamma technology is not restricted. This scenario would create a negative impact on the United States manufacturing environment.

ii) Cost of Building New Infrastructure

A movement to a different modality of radiation sterilization such as high energy x-ray will result in a considerable unwarranted cost and added complication to the medical device industry. This will be in the form of the closure and decommissioning of existing Cobalt-60 commercial gamma facilities, the constructing new facilities and transferring the sterilization process to the alternate source.

Based on the current extent and processing capability of existing cobalt-60 commercial gamma sterilization facilities in the United States, the replacement cost of the existing facilities, if mandated, can be conservatively estimated at US$15M each when including all building, site and equipment cost. This assumes that the new technology is equivalent in capital cost to a similar capacity cobalt-60 commercial gamma facility. This assumption, if applied to x-ray would, very likely, not hold true as the cost of producing high energy x-rays in commercial scale would require complex equipment. Regardless, if the costs were similar the value of the infrastructure replacement for 50 such facilities would be US$750M.

In this economic comparison of an x-ray system with a gamma irradiator, it is possible to load initially lower activity than the design capacity of the Cobalt-60 gamma irradiator. For example, an irradiator with a design capacity of 3 MCi can have an initial loading of one-third or less than the design limit, which provides for lower capital cost at the beginning of operations when the product volume would be expected to be lowest, thus allowing efficient economic scaling to occur over the life cycle of the facility. In contrast, the maximum throughput capacity, and associated capital cost, of an accelerator-based x-ray irradiator is generally installed at the beginning of the facility life, which makes it necessary to rapidly increase the product volume being processed, reaching the maximum potential volume capacity in a short time in order to maximize the economic benefit of the facility. This feature of Cobalt-60 gamma technology allows the owner to manage capital cost more to need than to the technology restrictions.

An added cost, which must be considered in an assumption of mandated transfer of technology, is the cost of decommissioning of the existing sites and removal and disposition of the installed Cobalt-60 sources. Current processing and disposition sites are in place to deal with the "end of useful life" removal; however, an accelerated schedule would cause extensive infrastructure investment in this area and could not be accomplished in a short period of time.

SECURITY OF COBALT-60 SEALED SOURCES AND IRRADIATORS

a) Cobalt-60 Irradiator Security

Safe and secure management of cobalt-60 commercial irradiators and sources have been a primary requirement for the irradiation industry for over five decades. These requirements have been created by closely working with regulatory bodies such as the United States Nuclear Regulatory Commission (US NRC) and the United States Department of Transportation (US DOT) to establish standards overseeing the production, handling, transport, use and life-cycle management of cobalt-60 radioactive sources.

A Cobalt-60 commercial gamma irradiator typically requires 1 to 5 million curies of cobalt-60 to provide the radiation levels necessary to process large volumes of product for sterilization purposes. Because of these high activity levels, irradiators provide an aspect of self-protection against malicious intent, as the radiation field strength is sufficient to give a fatal dose in a period of few minutes of exposure. Designed with substantial radiation shielding, typically composed of thick concrete walls, Cobalt-60 commercial irradiators utilize a series of interlocks and access control restrictions to prevent unauthorized access to the source area. Employees allowed to enter the source chamber are required to be trained and certified prior to granting access entry privileges.

As result of the unfortunate events occurring on September 11, 2001, Cobalt-60 commercial gamma irradiator facilities were placed in a heightened alert by a series of Safeguard and Threat Advisories designed to strengthen capabilities and readiness to respond to potential terrorist threats. This was soon followed by support for the United States to meet the newly revised International Atomic Energy Agency (IAEA) guidelines. The US NRC developed and instituted specific Compensatory Measures to further ensure the safety of these commercial Cobalt-60 gamma irradiator facilities. To these ends, security actions were embraced and adopted by the industrial irradiation community to achieve the goal of assuring that authorized users have adequate security and controls for radioactive materials to enhance deterrence, detection, and defence in response to threats, which includes;

- coordinating with law enforcement agencies in response to threats,
- requiring enhanced background screening of employees,
- fingerprinting authorized irradiator operators and other persons who may be granted unescorted

access to the areas where radioactive materials are used, stored, or transported,

- designating control entrance points for employees, visitors and contractors,
- issuing all employees identification badges,
- assigning escorts to visitors and contractors,
- providing employee training requiring notification of any unusual activity, behavior, or inquiries regarding the security systems or operational information, and reporting any unusual vehicles not expected at the facilities,
- instituting enhanced and supplemental access controls and interlocks to detect unauthorized intrusions with notification to pertinent authorities;
- controlling special tools and shipping containers for movement of cobalt-60,
- providing full life cycle management and tracking of cobalt-60 sources in a centralized database,
- implementing stricter import and export regulations, licensing, and controls.

b) Security Through Adequate Source Life-cycle Management Capability

Continued security against improper use of Cobalt-60 commercial gamma irradiator sources, requires that means for controlled, safe and effective life-cycle management of the radioactive material is provided at the end of its useful life, typically 20 years or more after initial installation. Source suppliers offer such services for sources that have decayed to levels below that which is useful in commercial Cobalt-60 gamma irradiators.

In order to forestall the potential abandonment of irradiator sources, the IAEA Code of Conduct institutes internationally a requirement that the US NRC and Agreement States have imposed for many years. Companies operating commercial Cobalt-60 gamma irradiators are required to provide financial surety instruments that would pay the state or federal government costs for decommissioning the irradiator facility and disposition of the sources in it. Historically, when commercial Cobalt-60 gamma irradiators have been closed and decommissioned, the sources have been transferred to other licensed irradiator facilities, which have easily accommodated the sources from the closed facility.

c) Cobalt-60 Transport Security

Cobalt-60 has been safely and securely transported for decades. Cumulatively, over 800 million curies (approximately 80,000 sources) of cobalt-60 have been transported without any in-transit accident with serious human health, economic or environmental consequences attributable to the radioactive nature of the goods. Safety of these radioactive material shipments is supported by the design and transport specifications of the shipping containers, which must be specifically evaluated and licensed by a national competent authority following guidelines established by the IAEA. These guidelines include multiple physical tests, which the container must undergo to prove that that it is able to maintain its structural integrity under severe accident scenarios. The results of these tests are documented in a Safety Analysis Report, which must pass competent authority analysis before a licence is issued.

Security of irradiator sources in transportation is enhanced by the inherent difficulty in moving containers weighing many tons and requiring special lifting provisions. Further, requirements established by regulators in the United States require the shipper and carriers of Cobalt-60 to have established security plans in place. In addition, regulatory oversight of transportation includes specific requirements for companies carrying these shipping containers, including required training for safety, security, and specific handling precautions, fingerprinting and background investigation for drivers or other persons allowed unescorted access to the materials in transportation, and specific controls on shipments from the point of origin to final destination, including, but not limited to;

- coordination of the shipment of a highway route controlled quantity (>27 kCi) begins weeks prior to actual shipment with confidential notification and established route plans to regulators and State agencies,
- notifications to regulators just prior to, during, and upon completion of shipment,
- regular communication between the two drivers and both the shipper and the State Police during transit,
- CVSA Level VI vehicle inspections conducted by specially trained State Police officers, and
- tracking systems to maintain information on vehicles throughout the shipment.

d) Ongoing Industry Support

The gamma-processing industry is supportive of regulatory initiatives that protect Cobalt-60 sources from malicious use, although it is believed these initiatives need to be logical, balanced, and harmonized in a manner that acts in the best interest of benefit of a global society. The users for this purpose, regardless of the security or risk classification systems used, agree these sources necessitate the highest level of protection to prevent unauthorized access and acquisition. Through the design of commercial Cobalt-60 gamma irradiation facilities, stringent control over the shipping of Cobalt-60 sources and detailed safety and security plans, gamma irradiator owners have implemented measures to ensure Cobalt-60 gamma irradiation continues to be safe and effective.

APPENDIX A

COMPARISON OF IRRADIATION TECHNOLOGIES

Executive Summary

Irradiation technology using photon interaction is currently accomplished by commercial gamma irradiators with cobalt-60 sources or x-ray irradiators with an accelerator-based source. The relative efficiency of the two technologies can be compared by evaluating the power utilization of each method in processing the same annual volume throughput of product.

Power utilization in commercial gamma irradiators using cobalt-60 is a function of the number of gamma photons resulting from radioactive decay and the number of those photons that interact with biological species resident on products. Consequently, the power supply in this type of system would constitute the radioactive sources themselves, with the operational power cost being replenishment of activity lost by radioactive decay.

In contrast, an x-ray irradiator system uses electrical power to generate radiation through electron interactions with a target material. Power utilization in such a system would not only incorporate the number of photons interacting with resident biological species, but also the relative efficiency of generating radiation as a function of the amount of electricity consumed.

In this context, the power utilization of cobalt-60 is higher than that of x-ray irradiator technology, which in turn leads to lower operational costs for a commercial Cobalt-60 gamma irradiator than has been observed for x-ray irradiators.

Assuming an annual rate of 5% downtime for both x-ray systems and gamma systems, and a minimum absorbed dose of 25 kGy, the power equivalence ratio on the basis of volumetric throughput is approximately 140 kW x-ray per 1 MCi cobalt-60. This appendix presents the technical evaluation supporting this comparison.

Power Conversion

One comparison that can be made between industrial irradiators using radioactive sources and accelerator sources is the evaluation of processing throughput on the basis of power output equivalence. In the traditional approach, irradiator throughput for an accelerator-based system is compared to gamma irradiators by simple unit conversion of the output of cobalt-60, taken in mega-curies (MCi), into the same units used to describe power output of the accelerator, given in kilowatts (kW). Given the photon energy of cobalt-60 emissions, the photon yield per radioactive transformation, and the assumed activity of 1 MCi, the conversion of units shows that 1 MCi of cobalt-60 gives a power output of 14.8 kW. Since the power output is related to volumetric throughput, this comparison is sometimes used to show that a 45 kW accelerator is approximately equivalent to a gamma irradiator with 3 MCi of cobalt-60.

However, the critical factor in comparing power output versus irradiator throughput is not necessarily the total amount emitted, but the amount that is beneficially intercepted by product being processed. Volumetric throughput values have been published for x-ray systems designed to irradiate full pallets of medical product[1] and for gamma irradiators also designed to irradiate full pallets of medical products.[2] These values are:

X-RAY				GAMMA			
25 kGy at 500 kW				25 kGy*			
	Throughput (m^3/hour)			Pallet	Throughput (m^3/hour-MCi)		
System	0.1 g/cm^3	0.2 g/cm^3	0.3 g/cm^3	System	0.1 g/cm^3	0.2 g/cm^3	0.3 g/cm^3
Palletron	9.0	8.0	7.0	Parallel	4.0	3.2	2.4
4-Pallet	14.0	11.0	9.0	7-Position	2.4	2.2	2.0
				8-Position	3.2	2.6	2.2

* Published data is for 20 kGy and has been normalized to 25 kGy for direct comparison purposes

Assuming an annual rate of 5% downtime for both x-ray systems and gamma systems, the power equivalence ratio on the basis of volumetric throughput is approximately 140 kW per 1 MCi cobalt-60, with some slight variation dependent on which set of values are compared directly.

Note that the estimated throughput for an x-ray system operating at 7.5 MeV is greater than that of a system operating at 5 MeV, on which the above values are based. Published theoretical studies[3] have estimated the increase in photon yield as 60% higher for 7.5 MeV versus 5 MeV. Assuming that this increase in photon yield translated into a direct increase in throughput, the power equivalence ratio on the basis of volumetric throughput at this energy is approximately 90 kW per 1 MCi cobalt-60.

Operational Cost Comparison

Making an operational cost estimate for x-ray systems for comparison to gamma irradiators necessarily entails an assumption as to conversion efficiency from the input power requirements of the accelerator to the final power output as x-rays for product irradiation. Assuming that a 5 MeV accelerator is used to produce x-rays, the conversion efficiency is most likely in the neighbourhood of approximately 8%, considering power losses in conversion of radiofrequency power to electron acceleration and in the x-ray target with power losses from those accelerated electrons during bremsstrahlung[3]. Taking the value stated above for volumetric throughput equivalence of x-ray power to cobalt-60 activity, the total power input requirements for the x-ray system to achieve the same volume throughput as 1 MCi cobalt-60 would be 2,800 kW, on the basis of comparing the

[1] Frederic Stichelbaut and Marshall Cleland, "High-Performance X-Ray Systems for Radiation Processing," presentation to National Academy of Sciences Radiation Source Use and Replacement Committee, December 8, 2006

[2] http://www.nordion.com/documents/elibrary/sterilization/pallet-irradiators/Pallet_Brochure.pdf

[3] J. Meissner, M. Abs, M. R. Cleland, A.S. Herer, Y. Jongen, F. Kuntz, A. Strasser, "X-ray Treatment at 5 MeV and Above," *Radiation Physics and Chemistry*, **57** (2000) 647±651

pallet systems as referenced in the preceding section. Different source-product configurations will have some differences in this ratio. Again assuming operations at only 5% downtime, the power consumption in this accelerator would be approximately 23,300,000 kW-h.

With the greater photon yield from 7.5 MeV x-ray generation as compared to 5 MeV, the electricity operational cost for the higher energy system would be lower as a function of volumetric throughput. This again assumes that the greater photon yield translates directly into increased throughput by the same percentage.

For comparison purposes to a gamma irradiator operating with 1 MCi cobalt-60, the annual loss in activity at that level would be 123 kCi, which would need to be replenished. The assumed cost of cobalt-60 is generally $2.00 per Curie, with that cost covering installation in the irradiator as well as acquisition of the radioisotope. The following table provides a summary comparison of the annual operating cost of these systems.

X-RAY			**GAMMA**	
Electricity Cost (US$/kW-h)	Power Utilization Cost			
	5 MeV	7.5 MeV	12.3%	decay per year
0.09	$1,365,000	$540,000	123,244	Ci/y decay, 1 MCi
0.10	$1,515,000	$600,000	$2.00	US$/Ci
0.11	$1,670,000	$660,000	$250,000	per year
0.12	$1,820,000	$720,000		

For more information, please contact:

Paul Gray

Chairman

613.592.3400 ext. 2483

paul.gray@nordion.com

or visit www.gipalliance.net for other GIPA fact sheets

Issued: November 2007