

GAMMA STERILIZATION

GIPA FACT SHEET

What is gamma processing?

Gamma processing refers to the sterilization of medical products by exposing them to measured doses of gamma radiation from Cobalt-60.

What is Cobalt-60?

Cobalt-60 (Co-60) is an intentionally produced radioactive metal. It is produced by placing Cobalt-59, a naturally-occurring non-radioactive metal, in a nuclear reactor where it absorbs neutrons and is converted into radioactive Cobalt-60. Cobalt-60 has a half-life of approximately five and a quarter years, which means that the activity (or intensity of gamma radiation emitted) reduces by 50% every five and a quarter years. Cobalt-60 decays into non-radioactive Nickel-60 by emitting gamma radiation.

How does gamma processing work?

Cobalt-60 radiation sources, sometimes called “source pencils” are usually comprised of small cylinders of Cobalt-60 metal doubly encapsulated in welded stainless steel tubes that meet international design standards to ensure they are fit for industrial applications.

When not in use, these source pencils are stored in deep pools filled with pure de-ionized water housed within gamma processing facilities or production (also called commercial) irradiators. Deep water provides an effective environmental shield for gamma radiation; it completely and harmlessly absorbs the radiation emitted from the Cobalt-60 pencils, protecting the people who are working inside the irradiation facility. Within the irradiation facility, the storage pool is located inside an irradiation chamber. The irradiation chamber is surrounded by thick concrete walls and ceiling, and has multiple inter-locked safety and security mechanisms that are activated to prevent access by personnel when the source pencils are raised out of the water pool during the gamma sterilization process.

To sterilize medical products, a source rack that contains the Cobalt-60 source pencils is raised mechanically out of the water pool into the center of the concrete irradiation chamber. The product to be processed is then transported by a conveyor mechanism (usually through a labyrinth entrance) into the chamber and exposed, for a defined period of time, to the ionizing gamma radiation emitted by the Cobalt-60 source pencils. This will reduce the microbial load on the medical device to the desired Sterility Assurance Level (SAL).

What kinds of products undergo gamma processing?

Gamma irradiation facilities use radioactive Cobalt-60 sources to sterilize many different types of single-use medical and dental products, including gloves, gowns, catheters, sutures, surgical drapes, syringes, etc. It is also used to sterilize a vast array of consumer products such as bandages, contact lens and lens' solution, hygiene products, and alcohol swabs.

Is it safe?

Researched extensively for more than 50 years, gamma processing has been proven to be safe and is recognized as safe and effective by international public health and government agencies such as the World Health Organization, the UN Food and Agriculture Organization, the U.S. Centres for Disease Control and Prevention and Health Canada.

Do irradiation facilities produce radioactive waste?

No. The irradiation facilities themselves cannot become radioactive, and they do not create radioactive waste. Cobalt-60 is manufactured in commercial nuclear reactors specifically for application in gamma processing and cancer therapy. Cobalt-60 pencils have a warranted lifetime of 20 years after which they, may be removed from the irradiation facility and shipped back to the original Cobalt-60 manufacturer, where they may then be re-encapsulated for a further 20 or 30 years of warranted use.

How much gamma sterilization takes place in the US?

In the US, over 50 large scale Cobalt-60 irradiators annually sterilize approximately 200 million cubic feet of medical items composed of thousands of different devices, including disposable (single-use), and implantable healthcare products representing approximately 45% to 50% of all sterile medical devices produced in the US.

How is Cobalt-60 transported?

Transportation occurs in specially designed steel containers that use either lead or depleted uranium to shield the environment from radiation during transport. The transport containers must meet strict design and performance requirements. They are designed to survive worst case accident scenarios, including intense fire and 9 metre drops onto an unyielding target. Testing is witnessed by the national competent authority (i.e. nuclear regulator) that issues design licenses on the basis of a satisfactory safety analysis report. Cobalt-60 is a non-soluble, non-fissile metal; and in the unlikely event that a transport container is breached and a doubly encapsulated source pencil is broken open, Cobalt-60 is not susceptible to dispersion into the environment. It should be noted that in over 50 years of use, there has never been a transportation incident resulting in human, economic or environmental consequences attributable to the radioactive nature of the goods.

Cobalt-60 sources are highly regulated at every stage of their life and multiple layers of control ensure that they are manufactured, transported, used and disposed of in a safe and secure manner. This inherent protection provides, for Highway Route Controlled Quantity (HRCQ) shipments of Cobalt-60 sources, a level of security and safety that is amongst the highest of any product transported on our roads and oceans today.

Can an accident at an irradiation facility lead to a “meltdown”, or release radiation that can contaminate the environment and endanger people?

No. It is impossible for a “meltdown” to occur in a gamma irradiator or for the radiation source to explode. Cobalt-60 is a non-fissile material. It cannot become “critical” or start a fission chain reaction, and it does not emit neutrons that could cause other materials to become radioactive. The walls of the irradiation chamber, the machinery inside the chamber, the pool water, and the product being processed cannot become radioactive. No radioactivity is released into the environment.

Cobalt-60 sources are not nuclear waste

Cobalt-60 sources and nuclear waste are sometimes categorized in a similar manner when safety and security regulations are created. This is because large quantities of Cobalt-60 sources are transported in protective containers similar to those used for nuclear waste, and require many of the same transportation administration procedures to be in place.

However, nuclear waste is comprised of a variety of fission products from nuclear power reactors (spent nuclear fuel) with wide-ranging residual energy levels and half lives, some as long as thousands of years. Nuclear waste is fissionable and can react with other materials.

On the other hand, Cobalt-60 sources for gamma sterilization are sealed in doubly encapsulated stainless steel tubes with well defined energy output and a relatively short half life of approximately five and a quarter years. A typical Cobalt-60 source will revert almost completely to non-radioactive Nickel-60 in about 100 years. The safety and security record of Cobalt-60 source production, transport, use and disposal is exemplary, based on a high degree of regulation and an industry focused on the beneficial use of this radioactive material. Cobalt-60 sources should not be considered as nuclear waste but as a product produced and used specifically for humanitarian applications: to support the medical and health care industries.

For more information, please contact:

Paul Gray, Chairman, GIPA
613.592.3400 ext. 2483
paul.gray@nordion.com

Updated: March 2014