Gamma Safe. Secure. Vital.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

GIPA
Gamma Industry Processing Alliance

GIPA White Paper: State Transportation Fees

Introduction:

The radioisotope Cobalt-60, supplied in sealed sources, is used in a wide variety of applications for the purposes of sterilizing single use medical products and consumer products. It is also used in other applications such as food irradiation.

Sterilization using Cobalt-60, often referred to as gamma sterilization, is a process of primary importance to the health care industry, having established itself as a manufacturing technology of choice over more than five decades.

The production, transport and use of Cobalt-60 sealed sources is highly regulated and over its history has demonstrated an exemplary safety and security record. Producers, shippers, carriers and users of Cobalt-60 must all meet stringent regulatory and licensing requirements, administered by national and local requirements derived from the International Atomic Energy Agency (IAEA) Safety Series Standards.

Globally, there are two primary suppliers of Cobalt-60. The largest supplier is Nordion Inc. based in Ottawa, Canada. The other is REVISS Services, based in the UK. Significant movement of Cobalt-60 sealed sources into the U.S. is therefore required for U.S. companies, who collectively produce and sterilize more than 50% of the global requirements for single use medical products. Transportation through the United States also takes place in instances where there is transshipment to Ports for offshore locations.

As the demand for Cobalt-60 sources continues to grow with the increasing demand for sterilization and radiation processing, and because the radioisotope Cobalt-60 decays over time, there is a need to ensure that a reliable, timely and cost efficient process is in place for the movement of this product which is so vital to the health care industry. Shipping occurs via road into and through the U.S. and via ocean for shipment from the U.S. or Canada to various Ports around the world, following which it is delivered by road to the end use customer. The U.S. is therefore a very significant participant in the use and transport of Cobalt-60.

Within the medical industry, there is a need for cost control in health care. The distribution and use of Cobalt-60 is governed by stringent regulatory measures, as well as effective safety and security controls that have been developed, and applied, by regulatory agencies and industry.

Under this protective regulatory umbrella, there is a need to ensure costs associated with the transport of Cobalt-60 are managed in a reasonable manner. This requires suppliers of Cobalt-60 sources to work closely with their supply chains. It also requires regulators to work together, with industry and with other agencies to minimize burdensome, compounding, and arguably, unnecessary costs. This paper will review Cobalt-60 applications, transportation of Cobalt-60, the regulatory environment in which it is shipped and the costs incurred in the movement of this important product. In particular, attention will be drawn to the safety envelope and the fees associated with CVSA Level VI inspections.

Cobalt – 60 Applications

Produced in power reactors throughout the world, Cobalt-60 emits high energy gamma rays that are used to eliminate harmful organisms in a variety of products.

Sterilization of Medical Devices

The medical device industry is a market worth over U.S. $150 billion and, with the health care field continuously growing, the need for safe and sterile products is more paramount than ever. The technology of choice for sterilization by many of the world's leading medical device manufacturers is gamma sterilization using Cobalt-60 contained within sealed sources.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

This simple process is safe, reliable, proven and highly effective in sterilizing single-use medical devices. Employed by the medical manufacturing industry for over 50 years, gamma sterilization is an environmentally preferred option to other sterilization modalities, including ethylene oxide (EO) and e-beam. With the ability to penetrate products while sealed in their final packaging, gamma sterilization economizes the manufacturing and distribution process, while ensuring full sterility of the product. It is estimated that greater than 45 percent of all single use medical products (surgeon's gloves, syringes, catheters, sutures, etc.) are sterilized using Cobalt-60. In addition, some medical products (such as tissues for transplant, plasma, alcohol swabs, and medical devices used for blood transfusion, endoscopic procedures as well as certain catheters) can only be sterilized with Cobalt-60. Finally, many consumer products are sterilized using Cobalt-60, from cosmetics to contact lenses and contact lens solution, to bandages and hygiene products. For a more complete listing of products sterilized with Cobalt-60, see Attachments A and B.

Sterilization of these products occurs in production (also called commercial) irradiators, large processing facilities that often operate twenty-four hours a day, seven days a week. These facilities utilize a conveyor system to move product into a protective biological shield where the product is exposed to a uniform dose of gamma energy (from the Cobalt-60) and sterilized. There are approximately 200 irradiators around the world with new facilities being designed and constructed yearly to keep up with the growing demand for sterile medical products.

Enhancing Food Safety by Irradiation

The process of food irradiation has been used in many areas of the world for more than five decades. As the world's food supply continues to globalize, there are new and exotic fruits and vegetables being introduced to foreign markets almost daily.

This accentuates the need to ensure the safety and quality of these new foods, which is becoming of critical importance. In 2007, the United States recalled 34 million pounds of beef due to E. coli. As a result, the idea of food safety in local markets has also garnered renewed attention.

Food irradiation is the process of exposing boxes or pallets of food products to radiation from a cobalt-60 source, electron beam, or x-ray. Lower doses of radiation delay ripening, inhibit sprouting, and extend shelf-life by reducing spoilage organisms in fruits and vegetables, helping to meet quarantine standards for export to foreign markets. Slightly higher doses are effective for the disinfestation of insects in food, eliminating the risk of introducing foreign insects to other countries. Higher doses significantly reduce or kill pathogens such as E.coli, listeria, and salmonella in seafood, meats, and poultry - substantially improving the safety of the food.

Food irradiation has been declared "safe and wholesome" by the World Health Organization (WHO) and the United States Food and Drug Administration (USFDA). Over 40 countries around the world have also approved the use of irradiation for more than 100 food types. In 2010 over 175 million pounds of spices and over 15 million pounds of ground beef and poultry were irradiated in the U.S., and with increasing amounts of legislation being promulgated each year approving food irradiation as a quarantine treatment for certain fruits and vegetables, food irradiation is poised for substantial growth.

Sterilization of Combination Products

Gamma sterilization with Cobalt-60 is well established as a reliable, effective process for the traditional medical device market. The next generation of medical devices is emerging, and gamma technology is poised to make a significant contribution in this exciting new market.

Combination products include drug device combinations and regenerative medicine products, where biological and pharmaceutical components are added to medical devices and natural or synthetic scaffolds in order to enhance device effectiveness or in some cases provide radical new treatments for disease by helping the body regenerate specific cells.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

The effects of gamma on traditional devices have been studied for many years and are well understood. Combination products incorporate biological materials that have typically not been treated with gamma due to compatibility issues. That said, the industry recognizes gamma technology as a simple, cost effective sterilization solution, so there is substantial investment being made in advancing the technology to allow for broader applications. In addition, these products are typically high value and low volume so that a different approach to sterilization may be required.

The industry is using its technical expertise in radiation physics and irradiator design to the development of patented technology for delivering the highly precise doses required by some of the next generation of medical devices. In addition, functionality such as temperature and environmental control and advanced dosimetry systems are being incorporated into new irradiator platforms that will serve both the development and small volume production markets, while being scalable to larger volumes.

Transportation of Cobalt-60

Over the past several decades, some 2000 road shipments of Cobalt-60 have occurred in the U.S. alone, significantly more if this is considered on a global basis. Over that time, the safety and security record for Cobalt-60 shipments has been exemplary, without any incidents which have adversely affected the public or the environment. There are many reasons for this enviable record:

- Regulatory Controls: This industry is highly regulated. International, National and State regulations govern all aspects of the Cobalt-60 life cycle. This includes aspects such as Cobalt-60 sealed source design, shipping container design, carriers' vehicles and tie-down procedures, in-transit monitoring and communications, driver training and security checks, licensing of the customer's facility and training of their staff.

- Source Design: Cobalt-60 sealed sources are designed to meet international regulatory standards established by the International Atomic Energy Agency (IAEA) and the International Standards Organization (ISO). As part of the design and qualification process, the sealed sources must undergo and pass a series of destructive tests prior to being licenced for manufacture and use. These tests and the licensing process fall under the jurisdiction of the competent authority in the country in which the sources are produced and used (i.e. United States Nuclear Regulatory Commission (USNRC), Canadian Nuclear Safety Commission (CNSC)).

- Transport Container Design: Transport containers must also meet stringent design performance requirements contained within the IAEA Transport Safety Regulations. As such, containers used to transport Cobalt-60 sources must also meet a series of performance test requirements at the design stage. These tests, normally conducted successively on the prototype container, involve design and package engineers from the design company, the user/shipper, the test laboratory, and the regulatory agencies involved in the licensing of the containers (i.e. USNRC, CNSC). Significant data is collected during the tests and a very detailed Safety Analysis Report is prepared which then is reviewed by the regulatory authority. Only if the prototype passes all of these tests and the Safety Analysis Report has been successfully defended and / or questions arising satisfactorily answered, will the container be licensed for use. Once licensed, the new containers to be used in transport are manufactured to a very strict and registered (with the competent authority) quality assurance plan.

- Container Use: a typical container used in the transportation of Cobalt-60 weighs approximately 12, 000 pounds. These containers can be used multiple times over their life span which can last for many years. However, prior to each and every use, the container is cleaned and undergoes a series of tests which ensure it is fit for service and meets the manufacturer's specifications which have been approved by the regulatory agencies. This rigorous inspection and preventative maintenance program ensures container integrity on an ongoing basis.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

- Training Programs: Shippers, carriers and end users of Cobalt-60 sealed sources must possess a level of knowledge which assures a clear and significant level of understanding regarding the nature, use and control needed to safely handle and move Cobalt-60. Formalized testing is often completed to ensure this level of knowledge exists.

- Administrative Controls: shipments of Cobalt-60 typically involve activities of greater than 27,000 Curies which makes them fall under additional safety and security regulations for "Highway Route Controlled Quantity" (HRCQ) shipments. Such shipments have specific requirements in place for the shipper and carrier of this activity. These requirements are detailed in USNRC issued regulatory & guidance documents. The additional safety and administrative controls relate to communications, real time monitoring, emergency procedures, and linkages to the NRC, DOT and individual States through which the shipment is traveling.

- Customs Controls: The U.S. Department of Homeland Security, Customs and Border Protection has a formal program in place entitled "Customs-Trade Partnership Against Terrorism" (C-TPAT). C-TPAT, as described in the C-TPAT website, "is a voluntary government-business initiative to build cooperative relationships that strengthen and improve overall international supply chain and U.S. border security. C-TPAT recognizes that U.S. Customs and Border Protection (CBP) can provide the highest level of cargo security only through close cooperation with the ultimate owners of the international supply chain such as importers, carriers, consolidators, licensed customs brokers, and manufacturers. Through this initiative, CBP is asking businesses to ensure the integrity of their security practices and communicate and verify the security guidelines of their business partners within the supply chain". Industries that are participating work through their supply chains to implement and verify security controls for the possession and handling of their shipments into the U.S. Nordion Inc., the primary supplier of Cobalt-60 into the U.S. is a top level validated C-TPAT member.

In addition, Nordion Inc. has fully met and been validated under the Canadian reciprocal to C-TPAT, the Partners in Protection (PIP) program. REVISS Services is also a top tier validated C-TPAT member as well as an AEO (Authorized Economic Operator) in the United Kingdom which is the UK equivalent to C-TPAT.

CVSA (Commercial Vehicle Safety Alliance)

In the "About CVSA" section of the CVSA website, CVSA describes itself as "an international not-for-profit organization comprised of local, state, provincial, territorial and federal motor carrier safety officials and industry representatives from the United States, Canada, and Mexico. Our mission is to promote commercial motor vehicle safety and security by providing leadership to enforcement, industry and policy makers. CVSA member jurisdictions are represented by various Departments of Transportation, Public Utility and Service Commissions, State Police, Highway Patrols, and Ministries of Transport. In addition, CVSA has several hundred associate members who are committed to helping the Alliance achieve its goals; uniformity, compatibility and reciprocity of commercial vehicle inspections, and enforcement activities throughout North America by individuals dedicated to highway safety and security."

CVSA is responsible for the development, implementation, training and administration of the "Level VI" program. This program is described in the CVSA website under "**North American Standard Inspection for Transuranic Waste and Highway Route Controlled Quantities (HRCQ) of Radioactive Material"** as **"**an inspection for select radiological shipments, which include inspection procedures, enhancements to the North American Standard Level I Inspection, radiological requirements, and the *North American Standard Out-of-Service Criteria for Transuranic Waste and Highway Route Controlled Quantities (HRCQ) of Radioactive Material".*

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

As of January 1, 2005, all vehicles and carriers transporting highway route controlled quantities (HRCQ) of radioactive material are regulated by the U.S. Department of Transportation and required to pass the North American Standard Level VI Inspection. Previously, U.S. Department of Energy (DOE) voluntarily complied with the North American Standard Level VI Inspection Program requirements. Select radiological shipments include highway route controlled quantities (HRCQ) of radioactive material as defined by Title 49 CFR Section 173.403."

Level VI Inspections

Under the Level VI program, State officials (i.e. Police, Highway Patrol, etc) are responsible for conducting a Level VI inspection at the point of entry into the U.S., of a vehicle carrying an HRCQ shipment. For Cobalt-60 shipments, this may be one of a number of border crossings between Canada and the U.S. or at the sea Port of entry. In addition, where HRCQ shipments are originating in the U.S. for movement to Canada or to a sea Port for export, the State in which the shipment starts will conduct the Level VI inspection.

Inspectors for the Level VI program receive standardized training from trainers who follow a strict and standard regimen. This ensures that there is consistency in application of the Level VI standards and consistency in the Level VI inspections at all locations in the U.S.

Upon successfully passing the Level VI inspection, the driver receives a decal which provides proof of that inspection. It is the intent of the Level VI program that an inspection is valid for the duration of the trip to the final destination. If there is a returning HRCQ shipment, a point of origin Level VI inspection will be conducted which is valid to the new final destination.

Industry Issue

Of concern to the industry is the frequency of multiple Level VI inspections on each trip segment. Although the point of origin or point of entry inspection should be adequate for the duration of that trip to final destination, GIPA members are routinely experiencing multiple inspections during each trip. These inspections may take place as soon as a few hundred miles or a few hours drive from the previous inspection. Multiple States have a policy of conducting a full Level VI inspection each and every time an HRCQ shipment transits through that State, regardless of whether or not that vehicle had passed a Level VI inspection in the previous State transited.

Level VI inspections are time consuming and costly to the industry (See Attachment C). Controls on HRCQ shipments include pre-approval of specific routes and estimated times of arrival at State lines, given that States want to know when the truck is entering and then leaving their jurisdiction. In addition, some States occasionally elect to escort these shipments and therefore need to know when to have their enforcement staff at the State border to meet the truck. Any delays en route, and additional Level VI inspections (typically taking 1 – 2 hours to complete) will cause the planned connection times to be missed, resulting in valuable State resources being ineffectively utilized. This can then result in additional problems and costs if the truck is forced to wait for enforcement personnel to arrive, or, if the timing is at change of shift, scheduling issues. Scheduling delays can also result in additional costs for rental of cranes and operating personnel as well as additional hours for source handling personnel at the destination. For more detail regarding the transportation of Cobalt-60 sources, see Attachment D (Typically Asked Questions Regarding Cobalt-60 shipments).

Proposed Resolution to the Issue

GIPA proposes that reciprocity be established regarding Level VI inspections. GIPA is of the view that the point of origin inspection meets the Level VI program requirements, that the quality of inspection will be consistent between States given the standardization of trainers and training material, and given the onerous training and examination procedures which must be met by those who conduct these inspections. Reciprocity would help to mitigate loss of time and inefficient use of expensive resources, whether that be the carriers' personnel and equipment, or the State enforcement personnel and resources en route. It would also mitigate the downstream costs to the recipient for delayed arrival and delay in delivery of critical products to the end user.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

GIPA industry members have been working and will continue to work with the CVSA and individual States to discuss and try to resolve the concerns and issues faced. In some cases, indications are that State legislation requires a Level VI inspection for each and every shipment through that State, with no mention and no consideration of such inspections being completed earlier in the trip (i.e. no recognition of reciprocity). Given the medical applications associated with Cobalt-60, any and all additional costs are ultimately borne by the health care industry or directly by the public. GIPA is looking for a means by which the intent of Level VI can be applied, while at the same time, mitigating the burdensome nature of multiple inspections which adversely impact cost of medical products used on a daily basis

Summary

States are unnecessarily imposing duplicative mandatory inspections and excessive associated fees on HRCQ quantities of Cobalt-60 en route from suppliers to industrial facilities in the United States engaged in the sterilization of a wide range of essential medical products.

Continuation of this practice has resulted and will continue to result in increased health- care costs and, in some cases, could render the gamma sterilization and microbial reduction process itself uneconomical. This may force the industry to migrate outside the U.S. which would result in the loss of hundreds or thousands of jobs.

The gamma sterilization industry recommends that there should be ***one mandatory*** CVSA Level VI inspection of each shipment of HRCQ of Cobalt-60 at the point of entry into the United States or at the point of origin in the United States. The extremely rigorous nature of the mandatory Level VI inspection and the stringent NRC/DOT requirements for HRCQ shipments of Cobalt-60 while in transit demonstrate that additional State inspections or escorts (and accompanying fees) are unnecessarily duplicative and result in nothing more than increased costs for gamma sterilization service providers and, thus, increased costs for health-care providers and medical product/device sellers and distributors.

Gamma sterilization and microbial reduction using Cobalt-60 sources has been and most often continues to be the preferred method established and utilized by government and industry for the sterilization of single use medical devices.

The gamma sterilization process' ability to penetrate large thicknesses of dense material provides extreme flexibility in product design, and this has led to the development of a wide range of essential medical devices that cannot be sterilized by other means. These products are central to health-care services in the United States and around the world.

Gamma sterilization has grown to the point where over 45% of the world's single-use sterile medical disposables are sterilized using this process. For example, over 80% of all surgeons' gloves are sterilized using Cobalt-60; in the U.S. alone, this amounts to some 200 million cubic feet of sterilized product annually. As such, gamma sterilization makes an essential contribution to the reliability and viability of the United States health-care system. The gamma sterilization process is conducted in some 56 domestic commercial irradiation facilities, each of which requires the frequent transport of new and used sources in interstate commerce. In addition, the United States is a primary transit point for Cobalt-60 being shipped to an additional 150 or so production irradiators around the world. Thus, worldwide sterilization services currently experience negative economic impacts due to the unnecessarily duplicative system of State inspections and escort and associated fees. Further, return of old or spent Cobalt-60 sources is also governed by these same requirements when transiting on the return route.

The domestic medical device gamma sterilization industry and the transportation of Cobalt-60 sources for use in irradiation facilities are strictly regulated by the NRC or its Agreement States and DOT. All aspects of the transportation process, from licensed, rigorously tested shipping containers to specially trained motor vehicle carriers to detailed and specific transport practices (redundant communication systems; dual drivers; detailed notification process pre-, during, and post trip; GPS and real time monitoring, etc.) are highly controlled under existing federal regulations. These controls have proven to be effective and such effectiveness is evidenced by the industry's exemplary safety and security record over the past five decades.

447 March Road
Ottawa, ON K2K 1X8 Canada
Tel: +1 613 762 0282
Fax: +1 613 592 9001
www.gipalliance.net

HRCQ shipments of Cobalt-60 sources currently are required to undergo a CVSA Level VI inspection prior to embarking on a particular shipment:

- Level VI inspections were originally intended for DOE Office of Civilian Radioactive Waste Management shipments;
- HRCQ shipment Level VI inspection process is accepted by regulators and an overwhelming majority of affected States, motor vehicle carriers, industry associations, and regional groups;
- Level VI decal approving shipment is good for *only one trip*;
- Once shipment reaches its destination, if it takes HRCQ of Cobalt-60 sources back, another inspection is required;
- After the attacks of September 11, 2001 the gamma sterilization industry implemented additional security measures, including NRC certification and registration of Cobalt -60 suppliers and users, "cradle to grave" tracking systems for Cobalt-60 sources; and provisions to ensure the tracking and proper disposal of Cobalt-60 in the event that a registered user declares bankruptcy and/or goes out of business;
- Cobalt-60 used in commercial irradiators is not an attractive terrorist target:
    - The non dispersible, non-flammable nature of Cobalt-60 is not conducive to a radiological dispersal terrorist device;
    - The inherently high radiation levels make the handling of Cobalt-60 (without significant infrastructure) virtually impossible;
    - Storage is in a controlled and protected infrastructure, routinely subject to regulatory review & inspection;
    - Transport is controlled and tracked throughout the trip.

Conclusion

Cobalt-60 is highly regulated at every stage of its life and multiple layers of controls ensure that it is manufactured, transported, used and disposed of in a safe and secure manner.

These inherent methods of control and protection provide significant security for HRCQ shipments of Cobalt-60, leading to the exemplary safety & security record of the industry.

The imposition of inspections and escorts and associated fees by States, which are duplicative of federally required Level VI inspections prior to the commencement of shipping, pose a significant burden on the gamma sterilization industry.

Duplicative inspections should be eliminated to reduce unnecessary cost burden to industry, and ultimately, to healthcare.

Attachments:

A – Medical Products Commonly Gamma Processed

B – Products Effectively Sterilized by Gamma

C – State Fees

D – Typically Asked Questions Regarding Cobalt-60 Shipments

For further information, please contact

Paul Gray

Chairman, GIPA

613.592.3400 ext. 2483

paul.gray@nordion.com

Or visit www.gipalliance.net for other GIPA Fact Sheets

Updated: March 2014