Gamma Safe. Secure. Vital.

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GIPA
Gamma Industry Processing Alliance

TRANSPORTATION SECURITY OF COBALT-60 USED IN RADIATION PROCESSING

GIPA FACT SHEET

SUMMARY

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.

This inherent protection, in most cases, provides greater security for HRCQ shipments of Cobalt-60 sources than that required for the shipment of radioisotopes for other uses in the United States.

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

REGULATION

The USA 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 the DOT. All aspects of the transportation process, from licensed, rigorously tested shipping containers, to specially trained and certified motor vehicle carriers, to detailed and specific transport practices (redundant communication systems; dual drivers; pre-trip, during and post arrival detailed notification processes; 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 plus decades.

After the attacks of September 11th, 2001, the gamma sterilization industry implemented additional security measures, including enhanced NRC certification and registration of Cobalt-60 suppliers and users, manufacturing and transportation tracking systems for Cobalt-60 sources; and provisions to ensure the tracking and proper disposal of Cobalt-60, including the unlikely event that a registered user declares bankruptcy and goes out of business.

After use, Cobalt-60 sources are not typically disposed of in the United States, but rather they are shipped back to their producer, either Nordion Inc., Canada or REVISS Services, United Kingdom.

COBALT-60 PHYSICAL PROPERTIES

Cobalt-60 used in Production (also called Commercial) Irradiators is not an attractive terrorist target:

- The non dispersible, non-flammable nature of Cobalt-60 is not conducive to its use in a radiological dispersal/terrorist device; and
- The inherently high radiation levels make the handling of Cobalt-60 (without significant infrastructure) virtually impossible;
- Access and physical security controls and routine regulatory inspections are stringent and significant.

TRANSPORT INSPECTIONS

Some States are unnecessarily imposing or are proposing legislation which will institute duplicative mandatory inspections and excessive associated fees on HRCQ quantities of Cobalt-60 en route from suppliers to industrial facilities in the United States (used for sterilization of a wide range of essential medical products and/or microbial reduction purposes) or HRCQ quantities of old or spent Co-60 en route back to the supplier for disposal purposes.

Continuation of this practice could result in an unnecessary increase in health-care costs and, in some cases, possibly render the gamma sterilization and microbial reduction process itself uneconomical. This may force parts of the healthcare industry to migrate outside the U.S. and result in the loss of jobs.

HRCQ shipments of Cobalt-60 sources currently are required to undergo a CVSA Level VI inspection prior to embarkation within the US or at the point of entry into the US and are valid for a one way transit to the final destination. The gamma sterilization industry agrees 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 or Canada. Industry recognizes and is willing to accept the cost incurred with this inspection, as it does with all other safety and security related costs incurred in assuring compliance with the specific requirements set by the US NRC and DOT for the transportation of Cobalt-60. The extremely rigorous nature of this 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 to the extent that any State fees can be justified, they should be nominal. Unneeded State imposed fees 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.

Transportation controls for HRCQ shipments of Cobalt-60 are numerous and redundant, including:

- Pre-established routes;
- Pre-trip notifications to NRC, DOT and individual States on the selected transport route;
- Emergency preparedness plans;
- Ongoing communication between driver and State authorities while en route;
- Post-arrival notification to NRC/Agreement States and DOT on arrival;
- Dual means of communication aboard truck;
- Dual drivers so truck shipments are never left unattended throughout trip;
- GPS; real time tracking; and numerous other controls.

Additional controls inherent in the C-TPAT, FAST, and PIP (Canadian equivalent to C-TPAT) programs further mitigate the risks of adverse events for Cobalt-60 shipments. These programs also require submission to the governing regulatory agency (e.g. CBP, DHS, CBSA) and regular audits or reviews by these agencies to ensure compliance, and accuracy of submissions are completed.

INDUSTRY BACKGROUND

For over 50 years, gamma sterilization and microbial reduction using Cobalt-60 sources has been the preferred method established and utilized by government and industry for the sterilization of single use (disposable) 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 evolution 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.

As a result, gamma sterilization has grown to the point where over 45% of the world's single-use sterile medical disposables are sterilized using the gamma sterilization 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 for use in the United States and for export. As such, gamma sterilization makes an essential contribution to the reliability and viability of the United States health-care system. (See GIPA Factsheet on Products Gamma Sterilized).

The gamma sterilization process is conducted in approximately 50 U.S. domestic commercial production irradiation facilities, each of which requires the regular transport of new and used sources in interstate commerce.

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