

Gamma

Safe. Secure. Vital.



Gamma Industry Processing Alliance



COUNCIL OF STATE GOVERNMENTS - SOUTHERN STATES ENERGY BOARD RADIOACTIVE MATERIALS TRANSPORTATION COMMITTEE

MIAMI, FLORIDA
November 17, 2011

WHO IS GIPA?



Gamma Industry Processing Alliance

- **An alliance created to advocate the development of responsible regulations that enhance the safe and secure management of Cobalt-60 sources and related irradiation processing facilities**

WHO IS GIPA?



Gamma Industry Processing Alliance

- Alliance made up of 15 companies from the Medical Device Manufacturers, Cobalt 60 source manufacturers and one industrial processing company
- Specific members typically function as contacts or representatives to regulatory bodies, such as the USNRC, on behalf of major gamma processing facilities within the U.S.
- Member of International Irradiation Association (iiA)

WORLD SUPPLIERS OF COBALT 60



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- **Nordion Inc. is based in Ottawa, Canada**
- **Reviss Services (UK) Ltd. Is based in Chesham, Buckinghamshire, UK**
- **Both companies supply the world with Cobalt 60 for the prevention and treatment of disease**
- **Approximately 50-60 shipments into/through the U.S. on an annual basis**

- **Cobalt 60 pencils emit gamma radiation - this energy is harnessed to eliminate pathogens and microbes**
- **Cobalt 60:**
 - **A solid metal**
 - **Non-fissionable**
 - **Non-soluble**
 - **Non-flammable**
 - **Long half-life**
 - **Large quantities per containers**
 - **Source and containers licensed**

IMPORTANCE OF COBALT 60



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- **Depended upon to sterilize ~45% of all single-use medical supplies in the world**
- **Certain products can only be sterilized with Cobalt 60**
- **Many products are optimally sterilized with Cobalt 60**
- **Sterilization of lab ware necessary for drug development and delivery**
- **Enhancement of food safety and preservation**
- **US customers produce ~ 50% of the world's single-use medical disposable products**

COBALT 60 STERILIZATION CAPACITY



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- **irradiator capacity is based on projected product sterilization needs and isotope decay**
- **No excess Cobalt 60 is maintained in irradiators**
- **Irradiators operate on a 24/7 schedule to optimize utilization of Cobalt 60**
- **Increase in sterilization demand for Health and Human Services would require additional Cobalt 60**

MEDICAL DEVICE INVENTORIES



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- **Most medical device companies practice JIT manufacturing**
- **Inventories in the order of less than 30 days are common**
- **Low inventories help control healthcare costs**
- **Disruption of the supply of Cobalt 60 will result in backorders of sterile single-use devices and potentially adverse impact on health care in the US and globally**

- **Limited number of Cobalt 60 suppliers**
- **U.S. is both a major user of Cobalt 60 and exporter of sterile product**
 - **50% of the world's sterile single-use medical devices supplied from the U.S.**
- **U.S. is a major transshipment point for Cobalt 60 to the rest of the world**
- **Efficient cross border carriage is critical**
- **Supply chain is highly regulated**
- **Safety and security integrated throughout**

TYPE B (U) PACKAGES



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- **Large in size and weight**
- **Capable of holding large quantities of radioisotope (Cobalt 60)**
- **Ship to U.S. sterilization facilities and to ports for export to overseas destinations**
 - **road and ocean transport**

SAFETY AND SECURITY



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- **How can we be assured these products and shipments are safe and secure?**

- **Source/container design**
- **Testing**
 - **NO loss of radioactive material is allowed following container or source testing**
- **Licensing**
 - **Packages are licensed by the competent authority of the country of manufacture (i.e. CNSC)**
 - **Packages are subsequently licensed by other competent authorities (i.e. USNRC and US DOT)**
 - **Packages are designed to contain large quantities of radioactive material and must meet the Accident Conditions of Transport standard**

PACKAGE VS CONTENTS



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- **Package has steel-covered fire shields for thermal protection**
- **Steel fins dissipate heat during normal conditions of transport and provide impact protection**
- **11 inches of lead shielding, encased in steel for radiation protection**
- **Holder containing double-encapsulated sealed sources**
- **Gross weight: 5445 kgs (12,000 lbs)**
- **Net weight : average 2.0 kgs (4 lbs)**

TRANSPORT EXPERIENCE



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“Over several decades of transport, there has never been an in-transit accident with serious human health, economic or environmental consequences attributable to the radioactive nature of the goods.”

IAEA International Conference on the Safety of Transport of Radioactive Material, 2003

ADMINISTRATIVE CONTROLS



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- **Regulatory Compliance**
 - **FMCSA- Routing requirements**
 - **USNRC- SGI**
 - Notification/monitoring prior to/during and post shipment
 - **CVSA – Inspections**
 - **STATE – Escorts and additional inspections**
 - **Import/Export Controls**
- **Customs Programs (C-TPAT, PIP, FAST)**

MORE ADMINISTRATIVE CONTROLS



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- **Licensing:**
 - **supplier, customer, carrier, sources, containers, operations**
- **Preparedness**
- **Carrier certifications**
- **Supply Chain knowledge**
- **Supply Chain security programs and personnel validation**

- **Population Density**
- **Emergency Response capabilities**
- **Exposure and other risk factors**
- **Most direct route unless an alternate route is safer**
- **Effects on commerce**
 - **shall not create an unreasonable burden on interstate or intrastate commerce**
- **Delays in transportation**

- **Pre-shipment notifications to NRC/DOT/In-Transit and receiving States**
- **Team Drivers**
- **Multi-mode communication (cell phone, computer)**
- **GPS/Real time tracking**
- **Stops at only secure locations en route**
- **Truck never left unattended**
- **Post arrival notification**

- **Shipments of HRCQ Radioactive Material require CVSA Point of Origin Level VI Inspection**
- **En-Route Inspections**
 - many States conduct additional inspections while shipment is en route. These inspections may or may not be Level VI.

STATE CONTROLS



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- **State designated routes**
- **Additional inspections**
- **Escorts**

- **Lack of Federal or State safe havens along state designated routes**
 - Part 37 of NRC regulations
- **Lack of reciprocity between States with respect to Level VI inspections**
- **Escort and State Fees**

- **Only healthcare providers can define life threatening medical conditions**
- **Backorders will result in shortages of critical medical devices**
- **Healthcare facilities do not have substitutes for these medical devices**
- **Shortages of medical devices can result in irreversible medical complications including death**
- **Additional costs associated with the transportation of Cobalt 60, drive up the costs of sterilization which in turn increases the cost of healthcare**

- Growth in demand for Cobalt-60
 - new applications
 - aging population
 - increased access to healthcare
 - increased consumer goods demand
 - limited healthcare dollars and spending available
- Sterilization will continue to be a critical process in the medical products manufacturing industry

PARTNERSHIP



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- **Continue to communicate and work together to facilitate safe and secure Cobalt 60 shipments**

QUESTIONS



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CONTACT INFORMATION



Gamma Industry Processing Alliance

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