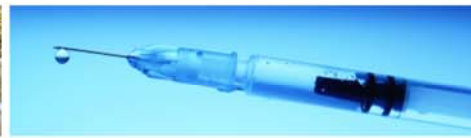


Gamma

Safe. Secure. Vital.



Gamma Industry Processing Alliance



NATIONAL STAKEHOLDERS TRANSPORTATION FORUM

DENVER MAY 12, 2011

WHO IS GIPA?



Gamma Industry Processing Alliance

- Alliance made up of 15 companies from the Medical Device Manufacturers, Cobalt source manufacturers and one industrial processing company
- Represents all the major gamma processing facilities within the US to the regulatory bodies such as the USNRC.
- Member of International Irradiation Association (iiA)

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.

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



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- **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 container**
 - **Sources 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**
(e.g. endoscopic/blood gathering products, alcohol swabs, biological materials for transport)
- **Necessary for drug development and delivery (sterile lab ware)**
- **Relied upon to enhance food safety & preservation**
- **Blood transfusions – to prevent GVHD**
- **Treating cancer (45,000 treatments/day in > 50 countries)**

COBALT 60 STERILIZATION CAPACITY



Gamma Industry Processing Alliance

- **Sterilization capacity is based on projected product 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



Gamma Industry Processing Alliance

- **Most medical device companies practice JIT manufacturing**
- **Inventories in the order of 30-40 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**

SUPPLY CHAIN



Gamma Industry Processing Alliance

- **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



Gamma Industry Processing Alliance

- **Large in size and weight**
- **Capable of holding large quantities of radioisotope**
- **Ship to U.S. sterilization facilities and 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?**

ENGINEERING CONTROLS



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- **Source/container design**
- **Testing**
- **Licensing**

TESTING OBJECTIVE



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- **NO Loss of radioactive material is allowed following container or source testing**

SEALED SOURCE TESTING



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- **Sealed sources must meet, as a minimum, the following tests:**
 - **Impact Test**
 - **Bend Test**
 - **High temperature test**
- **After all tests, the source must still retain its leak tightness in order to be certified**

TRANSPORT PACKAGES



Gamma Industry Processing Alliance

- **Packages are licensed by the competent authority of the country of manufacture**
- **Packages are subsequently licensed by other competent authorities (USNRC, DOT, etc.)**
- **Packages are designed to contain large quantities of radioactive material and must meet the Accident Conditions of Transport standard**

PACKAGE TESTING



Gamma Industry Processing Alliance

- **Containers must be able to withstand potential accident conditions**
- **Mechanical Test (2)**
 - package is dropped from a height of 9 meters onto an unyielding target in the worst possible orientation
- - package is dropped in the worst possible orientation from a height of 4 feet onto a solid steel bar mounted onto an unyielding target
- **Thermal Test**
 - The package shall be subjected to a fully engulfing fire at 800° C (1472° F) for a period of 30 minutes

PACKAGE VS CONTENTS



Gamma Industry Processing Alliance

- **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 : approx. 2.0 kgs (4 lbs)**

TRANSPORT EXPERIENCE



Gamma Industry Processing Alliance

“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



Gamma Industry Processing Alliance

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

MORE ADMINISTRATIVE CONTROLS



Gamma Industry Processing Alliance

- **Licensing:**
 - **supplier, customer, carrier, sources, containers, operations**
- **Preparedness**
- **Carrier certifications**
- **Supply Chain knowledge**

- **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/Transiting 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 en route. May or may not be Level VI.**

STATE CONTROLS



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

- **Lack of safe havens along state designated routes**
 - **Part 37 of NRC regulations**
- **Lack of reciprocity between states with respect to Level VI inspections**
- **Escort Fees**
 - e.g. \$1800/flask + \$25.00/flask/mile for every mile over 200 miles travelled within the state vs. flat fee per vehicle translates into several thousand dollars added to transport costs

IMPACT ON HEALTHCARE



Gamma Industry Processing Alliance

- **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 then increases the cost of healthcare**

FUTURE



Gamma Industry Processing Alliance

- **Demand for Cobalt -60 is growing**
 - **New applications**
 - **Aging population**
 - **Increased access to healthcare**
 - **Increased consumer goods demand**
 - **Limited healthcare dollars and spending available which is further impacted by increased shipping costs due to escort fees**

PARTNERSHIP



Gamma Industry Processing Alliance

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



Gamma Industry Processing Alliance

QUESTIONS ?

CONTACT INFORMATION



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