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

MIAMI, FLORIDA
November 17, 2011
WHO IS GIPA?

- 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?

- 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

- 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

- Dependened 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

- 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
• 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

- 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
• How can we be assured these products and shipments are safe and secure?
ENGINEERING CONTROLS

- 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 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)
“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.”

ADMINISTRATIVE CONTROLS

• 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

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

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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
CVSA

- 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

- State designated routes
- Additional inspections
- Escorts
ISSUES

• 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
IMPACT ON HEALTHCARE

- 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
FUTURE

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