NATIONAL STAKEHOLDERS TRANSPORTATION FORUM

DENVER MAY 12, 2011
WHO IS GIPA?

- 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?

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

- 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

- 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

- 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)
• 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
• 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
• 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
- Ship to U.S. sterilization facilities and ports for export to overseas destinations
  - road and ocean transport
• How can we be assured these products and shipments are safe and secure?
• Source/container design
• Testing
• Licensing
TESTING OBJECTIVE

- NO Loss of radioactive material is allowed following container or source testing
SEALED SOURCE TESTING

- 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

- 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.
• 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 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)
“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
  - 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
- 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
USNRC

- 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

- 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

- 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
• 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
• Continue to communicate and work together to facilitate safe and secure Cobalt 60 shipments
QUESTIONS ?
CONTACT INFORMATION

• Nordion (Canada) Inc.
  Barbara Englehart
  T: 613-592-3400 ext.2171
  F: 613-591-6623
  E: barbara.englehart@nordion.com

• Reviss Services – U.S. Office
  John Schrader
  T: 847-680-4522
  F: 847-680-5159
  E: john.schrader@reviss.com