



INTERNATIONAL SOURCE SUPPLIERS
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Denial of Shipment of Radioactive Materials

International Ports and Harbour Exhibition
May 25 – 29, 2009

Grant Malkoske, Chairman ISSPA
Paul Gray, International Steering Committee



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ISSPA's Mission

- To ensure that the beneficial use of radioactive sources continues to be a safe and secure technology for medical, industrial, and research applications
- To provide technical expertise to assist and facilitate the management of disused sources

Membership:

- Fifteen members in 9 countries
- Represents more than 95% of radioactive sources produced/distributed globally
- Includes suppliers of equipment containing radioactive sources

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Radioactive Materials – Critical to Global Economy & Health

- Medical treatment, diagnostics, therapeutics and palliation
- Sterilization of single-use medical devices
- Research and development
- Nuclear Energy
- Electronics components (tantalum/niobium)
- Food safety and agricultural applications
- Industrial and safety applications (NDT of welds, pipelines, castings and engines)
- Law enforcement & counterterrorism

⇒ ***The radioisotope sector is broad and diverse, long established, and with a culture of safety and security***



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Importance of Radioisotopes and Equipment



- Cobalt-60 is depended upon to sterilize some 45% of all single-use medical supplies and devices in the world
 - sutures, catheters, syringes, heart valves, artificial joints and an estimated 80% of all surgeons' gloves
- Cobalt-60 is increasingly relied upon to enhance food safety and preservation
 - destroying e-coli
 - food for the immunocompromised
 - packaging treatment
- Ir-192 is used in radiography equipment for non-destructive testing of infrastructures





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Importance of Radioisotopes and Equipment



- Cobalt-60 is used for treating cancer (45,000 treatments/day in >50 countries)

- Caesium -137 is used in irradiation to prevent TA-GVHD following transfusions



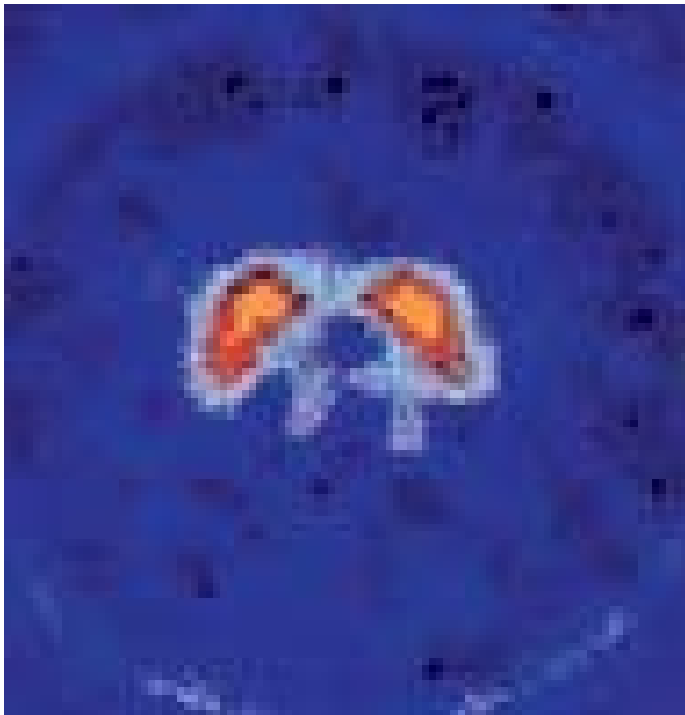
- Other applications of sources for level measurement, limit switches, oil well logging, density gauges, etc.



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Timely and Reliable Shipping is Critical



- Example: Nuclear Medicine Radioisotopes
- > 30 M applications per year in > 70 countries globally
- > 100 applications of medical scans to check anatomical function
- Radioisotopes are short-lived, making timely transport critical
- Increased global demand
- New therapies and diagnostics based on radioisotopes (e.g. radiomunotherapy for non-Hodgkin's lymphoma)

⇒ ***secure, reliable supply of medical isotopes is paramount to meet patient needs***



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Key Current Challenges for the Radioactive Sources Industry

- Isotope supplies from an ageing global reactor infrastructure
- Distribution (“denial of shipment”) due to security/regulatory constraints
- Increased regulatory burden (tracking, security, financial surety) exacerbated by competing/conflicting regulatory agencies and regulations
- Increased demand for disposal as sources approach the end of their working life and few national governments have a repository/disposal infrastructure in place
- Recycling in the context of regulatory constraints restricting the international shipment of materials that could be construed as waste



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IAEA International Steering Committee (ISC) Action Plan

Awareness	<ul style="list-style-type: none">▪ Institute a database to record all denials (all modes, all geographies)▪ Access data, define root cause of denials, establish action plan to resolve▪ Educate all parties involved of the very rigorous standards in place re transportation
Training	<ul style="list-style-type: none">▪ Improve awareness and understanding of transportation supply chain and stakeholders regarding transport safety regulations and experience
Communication	<ul style="list-style-type: none">▪ Improve the integration and transparency between producers, shippers, users, carriers, authorities, regulators and the Public
Lobbying	<ul style="list-style-type: none">▪ for marketing, outreach, and promotion of industries shipping radioactive materials and for promoting a positive image regarding the use of these materials
Economics	<ul style="list-style-type: none">▪ Mitigate deleterious & burdensome costs associated with shipping denials & delays
Harmonization	<ul style="list-style-type: none">▪ of international and national regulations and standards, of Port and Port Authority requirements, of carrier requirements and of the process used to report denials of shipments



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ISC Accomplishments

- Meeting in January 2009 reviewed causes for denials and re-focused Action plan
- 5 Regional Networks have been established
 - Mediterranean, Asia Pacific, Latin America, English and French speaking Africa
- More than 60 Member States have identified a National Focal Point
- ISC is collaborating with other international agencies
 - IMO, ICAO, IATA, IAPH
- ISC is also collaborating with industry associations
 - ISSPA, iiA, CORAR, AIPES



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In Review: IAEA Steering Committee

- Integrates industry, Member States and IAEA/IMO/ICAO
- National Focal Points (NFP) are single point of contact in Member States
- Regional Network and NFP assure local (country and regional) integration and ownership of denial issues, and global integration via ISC
- Aggressive action plans with ongoing high ISC focus (ISC Management Team conferences monthly)
- Proven experience - process is working
- High on priority list of IAEA and IMO with Board of Governors and GC updates



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Practical Results

- late 2007 – effected a change in regulatory position in one country which provided an ongoing ability to ship Cobalt-60 to a number of Asia Pacific countries
- mid 2008 – met with and changed a South American Port policy, providing an ability to ship into and out of that Port
- Increased awareness of the importance of not having any denial of shipment of Class 7 goods



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Moving to routine and consistent shipments globally





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Engagement of industry is a key success factor for Enhancing Safety and Security Culture

- To actively participate in developing strategies for the long term control and management of sources
- To collaborate with the IAEA in developing international policy matters
- To forge a strong partnership with national legislators and regulators
- To facilitate communication, education, and awareness amongst key stakeholders

⇒ ***as an industry, we take seriously our responsibility to ensure effective stewardship and self-management of our industry***



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In Conclusion

- Ideally, no denials, **HOWEVER**, likely that denials and delays will occur ... need system to mitigate
- Required system has now been established, is in use, and has been shown to work
- Denial and delay database is key to ultimately implementing appropriate corrective actions
- Regional Networks and NFP are critical
- Need Member State ongoing commitment to support work of IAEA ISC and overall action plan



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ISSPA Members

- Berthold Technologies GMBH & Co. KG
- BEST Theratronics
- Dioxitek - CNEA
- Eckert & Ziegler Isotope Products
- Elekta Instrument AB
- Endress + Hauser GmbH + Co. KG
- Federal State Unitary Enterprise “Mayak”
- Gamma-Service Recycling GmbH
- General Electric Healthcare
- Institute of Isotopes, Co. Ltd.
- International Isotopes Inc.
- MDS Nordion
- QSA Global GmbH
- Reviss Services UK Ltd.
- Varian Brachytherapy

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⇒ ***industry leaders ensuring the safe and secure design, manufacture and supply of radioactive sources and equipment***