ISSPA

INTERNATIONAL SOURCE SUPPLIERS AND PRODUCERS ASSOCIATION

SAFE AND SECURE AT THE SOURCE

PATRAM 2010, London, England

Safe and Secure Life Cycle Management of Radioactive Sealed Sources

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ISSPA's Mission

- To ensure that the beneficial use of radioactive sources continues to be regarded by the public, the media, legislators, and regulators as a safe, secure, viable technology for medical, industrial, and research applications

Membership:

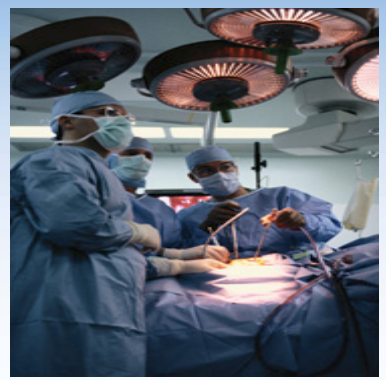
- Fifteen members in 9 countries
- Represents more than 95% of radioactive sources produced/distributed globally

Radioactive Materials – Vital Role in Promoting Public Health & Welfare

- Sterilization of single-use medical devices
- Medical treatment, diagnostics, therapeutics and palliation
- 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; oil well logging)
- Law enforcement & counterterrorism

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

Sizing the 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 immuno-compromised
  - packaging treatment
- Ir-192 is used in radiography equipment for non-destructive testing of infrastructures
  - availability of critical infrastructure depends on effective quality management processes

Sizing the 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.

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Challenges to the Continued Beneficial Use of Radioactive Sources

- Import/Export challenges resulting from competing/conflicting regulatory agencies or regulations and a lack of global harmonization to the Code of Conduct (tracking, security, consent authorizations)

  - Large number of End Users relative to Manufacturers requires Manufacturers to request a vast number of government to government consent authorizations which places a significant burden on both the Manufacturer and Regulatory Agency

  -Government to Government consent authorizations issued for short durations which may not support the time needed to develop a transportation and delivery plan

- Perceptions of risk to safety and security in the supply and use of radioactive sources
  - public and media concerns about “dirty bombs” and radiological dispersion devices

Challenges to the Continued Beneficial Use of Radioactive Sources

- Denial of shipments due to Supply chain restrictions
  - lack of awareness regarding the safety, security and benefits associated with use of radioactive materials
  - reluctance to handle radioactive materials by the transportation sector as a result of increased cost and effort needed to ensure compliance
- Unclear or conflicting regulatory requirements that may classify radioactive sources as radioactive waste could complicate or prevent the international transfer of radioactive sources back to a source manufacturer for end of life management
- Availability of suitable repositories/infrastructure to ensure safe and secure disposal or long term storage of sources that have reached the end of their useful life and can not be recycled

Challenges – Supply Chain Restrictions

- Limited number of Ports willing or authorized to handle Class 7 materials
- Limited number of carriers willing or authorized to handle Class 7 materials
- Limited number of Type B packages and no Type C packages dictates transportation schedules, mode, drives up costs for new and replacement sources and makes it difficult to recover orphaned sources
- Most direct routes may be bypassed to minimize transportation costs by reducing transportation user fees or escort fees
- Delay or denial of shipments increases the cost to industry and the consumer, reduces inventories of sterile products and increase the perception of risk associated with use of radioactive sources
- Package tracking technologies under consideration would increase costs and may reduce number of transportation routes and ports even further

A Record of Safety and Security

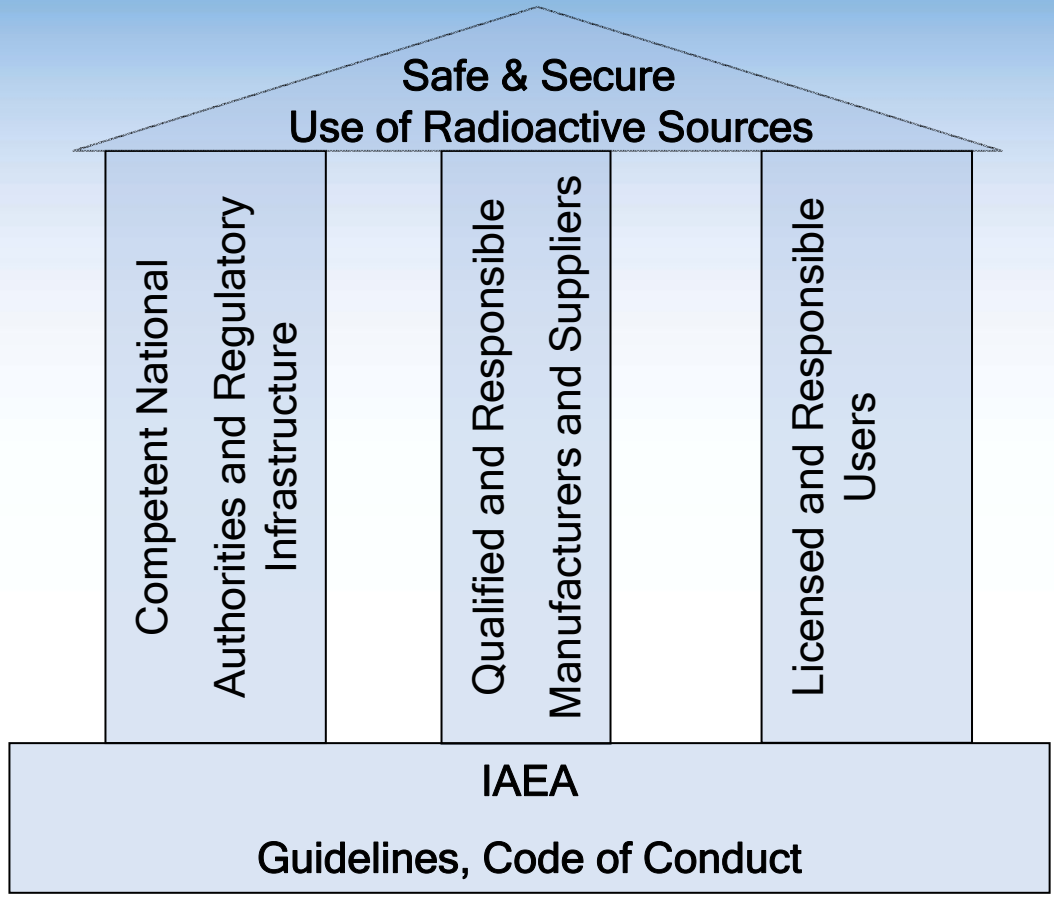
IAEA, 2003

> "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

Challenges - Long Term Management of Disused Sources

- Increased demand for disposal as sources approach the end of their working life and few national governments have a repository/disposal infrastructure in place
- Lack of licensed Transport Packages leads to long-term storage in lieu of proper disposal
- Security and safety risks associated with long term storage warrants investment in consolidation facilities (near term) and repositories (long term), yet funding at this time is difficult to obtain
- Regulatory constraints and high cost of repackaging and shipping sources with expired regulatory documentation (Special Form, Type B etc) would be alleviated by procedures authorizing “special arrangements” to ease/encourage return shipments of disused sources or sources at the end of useful life

A Source Life Cycle Management Model



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A strategic approach to a Safety and Security Culture for Sources and Equipment

- Life cycle source management is a cornerstone to strengthen the long term control of radioactive sources
  - manufacturers endorse the concept of cradle-to-grave source management
  - lack of State repository/disposal infrastructure and regulatory inconsistencies create undue burdens and disincentives for Manufacturers
- An integrated, system concept to source/equipment security is necessary for effective management of disused sources and to mitigate event consequences
  - manufacturers increasingly design-in safety, security and recyclability into systems.
  - recycling where this is technically and commercially viable

A strategic approach to a Safety and Security Culture for Sources and Equipment

- A risk-informed (graded) approach is fundamental to ensuring the effective security of sources and devices
  - based on risk, benefit, cost-effectiveness and practicability
  - ISSPA supports the concept of physical tracking of category 1 packages and administrative tracking of category 2 packages, but sources themselves cannot be tracked
- Regulators, manufacturers, suppliers and users all have specific, but complementary and overlapping roles and responsibilities

⇒ a means to ensure effective collaboration between all stakeholders is necessary to promulgate effective strategies

Engagement of industry:
a key success factor to Enhance a 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 develop comprehensive standards that facilitate global commerce
- 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***

Recommendations

- Strive to achieve worldwide implementation and harmonization of regulations
  - development of standards must continue
- Continue to foster co-operation between manufacturers and regulators
  - implementation of changes to facilitate the authorization and licensing process
- Establish a culture that applies a risk informed approach to safety and security
  - will help to ensure that cost-effective strategies are being employed
- Take a strategic approach to source safety, security and life cycle management
  - fundamental to strengthen long term control of sources

Conclusion

- Radioactive sources can and will provide a safe, secure, viable technology for medical, industrial and research applications for decades to come
- Regulators, Suppliers/Manufacturers and Users have overlapping and distinct responsibilities in regards to safety and security throughout the entire source life cycle
- Disposal options for disused radioactive sources must be commercially and readily available
- A robust safety and security culture is a societal benefit
  - this will ensure the continued beneficial application of radioactive sources and equipment

ISSPA Members:

- **Berthold Technologies GMBH & Co. KG**
- **Dioxitek - CNEA**
- **Eckert & Ziegler nuclitech GmbH**
- **Elekta Instrument AB**
- **Endress + Hauser GmbH + Co. KG**
- **Federal State Unitary Enterprise "Mayak"**
- **Gamma-Service Recycling GmbH**
- **Best Theratronics Ltd**
- **General Electric (Energy & Healthcare)**
- **Institute of Isotopes, Co. Ltd.**
- **International Isotopes Inc.**
- **MDS Nordion**
- **QSA Global Inc**
- **Reviss Services UK Ltd.**
- **Varian Brachytherapy**

www.isspa.com

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