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INTERNATIONAL SOURCE SUPPLIERS AND PRODUCERS ASSOCIATION

SAFE AND SECURE AT THE SOURCE

Options for Long Term Management of DSRS Return to commercial supplier

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ISSPA 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
- An association that is comprised of companies who are international industry leaders in the manufacture, production and supply of sealed radioactive sources and/or equipment that contain sealed radioactive sources as an integral component of the device.
- Members agree to a Code of Good Conduct which includes excellent regulatory compliance, QA and responsibility for management of sealed sources and devices

ISSPA Membership

Sixteen members in 9 countries

Represents more than 95% of radioactive sources produced/distributed globally

- Alpha Omega Services
- Berthold Technologies GmbH & Co. KG
- Best Theratronics Ltd
- Dioxitek - Comisión Nacional de Energia Atómica
- Eckert & Ziegler nuclitech GmbH
- Elekta Instrument AB
- Endress + Hauser GmbH + Co. KG
- Gamma-Service Recycling GmbH
- General Electric Healthcare
- Institute of Isotopes, Co. Ltd.
- International Isotopes Inc.
- Nordion Inc
- NTP Radioisotopes (Pty) Ltd
- QSA Global Inc
- Reviss Services UK Ltd.
- Varian Brachytherapy

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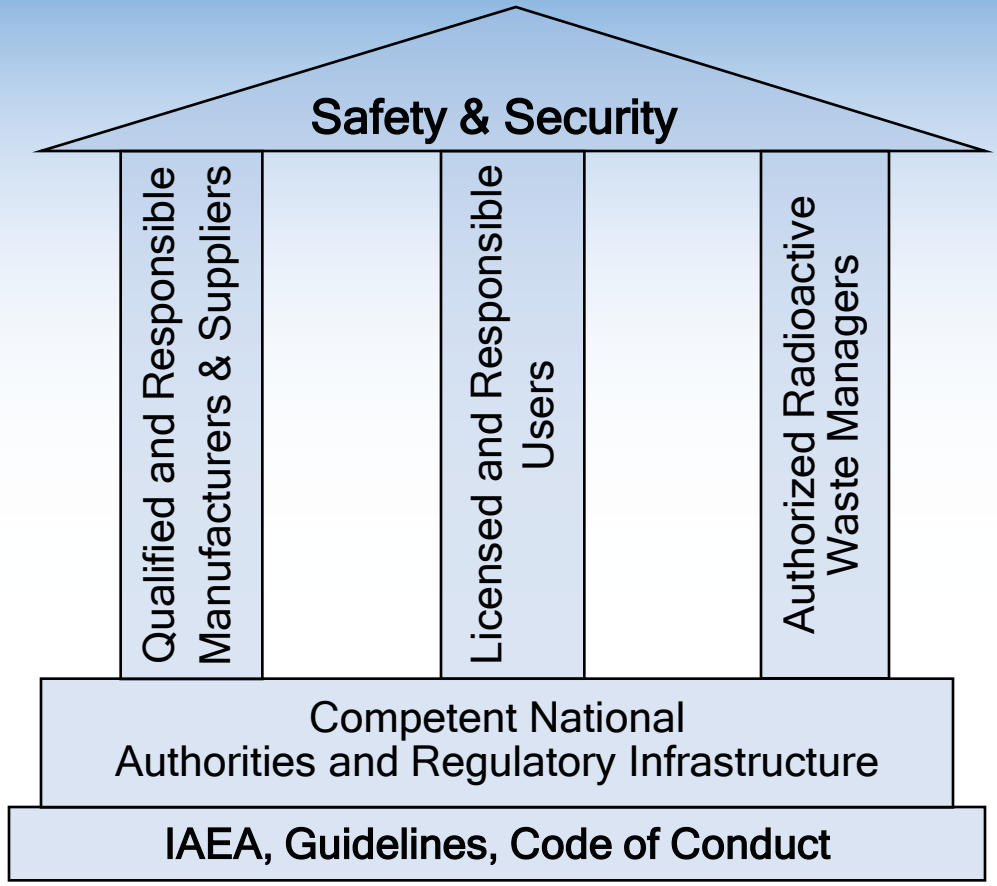
Overarching Policy Strategies

Radioactive Source Life Cycle Management



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DSRS Management Perspectives

- Volume of sealed sources is far less than 1% of all radioactive waste
- Sealed sources meeting ISO Classifications and Special Form Criteria have more structural integrity than typical wastes, much less susceptible to damage and degradation over time
- Sources can easily exceed initial recommended working life based on historical information
- Radioactive materials can be recovered from sources or re-encapsulated for reuse.

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Strategies - Long Term Management of DSRS

Recycle

Long Term Storage

Disposal

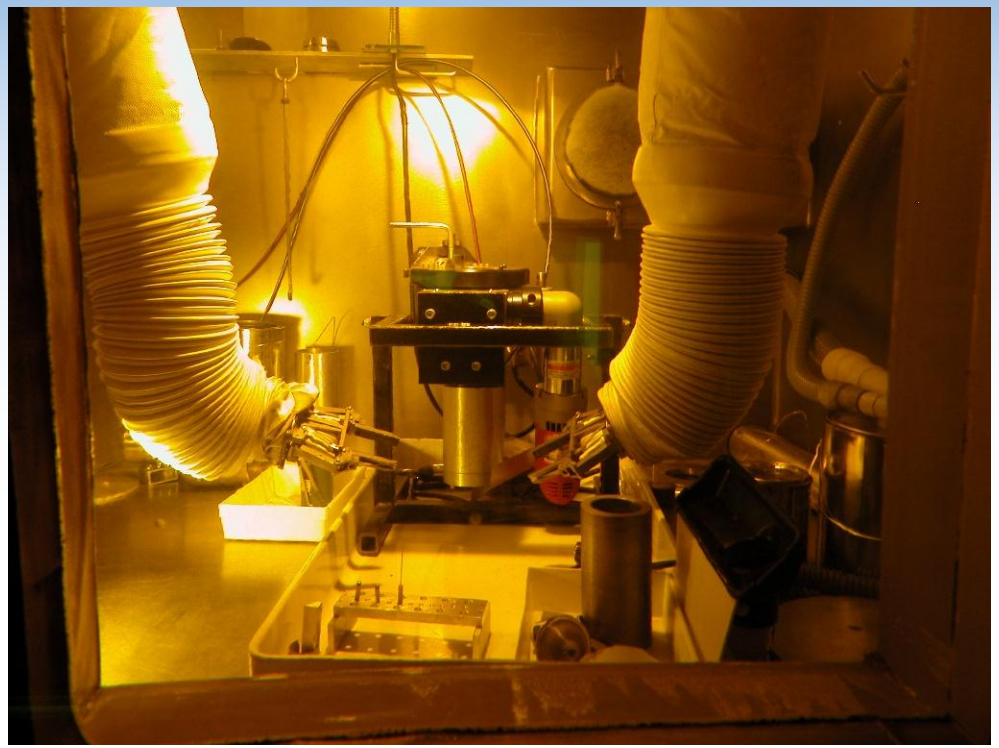
Recycle – Reutilization of Resources

Industry's Preferred Option

- Reduces the amount of radioactive material that needs to be produced.
- Must be cost effective and technically feasible for a commercial entity
- Various methods available

Recycle – Recover Material

- Source disassembly
  - Specialized equipment & qualified technicians
  - Recover material used as is or blended

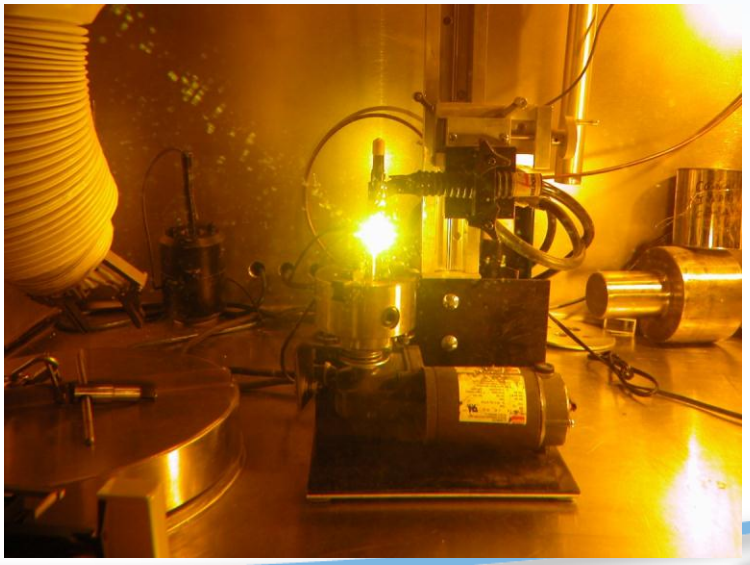


Recycle – “Re-Life” the Source

- Reutilize the source “as-is”
  - Inspection and Testing
  - Extend working-life
- Over encapsulation
  - Replace outer encapsulation
  - Over encapsulate entire source, use for new application

Recycle – “Re-life the Source”

Original design parameters, weld integrity, environmental conditions of use and potential gas build up must be considered.



Current Recycling Initiative

Several ISSPA Companies are actively recycling sources using all of the methods previously mentioned.

Questions regarding details on the extent should be directed to specific companies

Long Term Storage of DSRS

Not a Realistic Option for a Manufacturer

- Source manufacturers have robust security controls so LTS at the source manufacturer facility is feasible. Must consider:
- Liability issues associated with quantities possessed.
- Financial responsibility of eventual disposal
- Ultimate disposal path must be available

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Disposal

Not a viable option through a source manufacturer

- Source manufacturers do not operate as waste brokers.
- Licensing and regulatory restrictions would greatly limit this.
- Disposal site availability, should one exist, may also be limited by legislatively imposed restrictions, i.e. waste generator or country of origin restrictions.

Disposal

- Lack of disposal options hinders end of life management of DSRS
- It is imperative that repositories are available for the safe and secure disposal of DSRS. In the end there will be material and sources that require disposal. Source suppliers are in no position to solve this problem.

Challenges to effective DSRS management

Regardless of which end of life management option is selected the biggest challenge that we all face is simply getting a DSRS from Country A to Country B.

- Source Pedigree
- Transportation Cost & Logistics
- Container Availability
- Additional Requirements

Challenges – Source Pedigree

Return to Original Manufacturer

- It is industry's position that a sealed source should be returned to any source manufacturer capable of safely handling and managing it.
- This position also addresses issues that arise when the original source manufacturer is no longer in business or authorized to possess the source.

Challenges – Source Pedigree

Country of Origin – difficult to ascertain

- Sources may contain components from multiple countries.
- Some companies have manufacturing facilities in several countries, the source design/certificate may be held by a single division of the company further complicates the meaning of country of origin.

Challenges – Source Pedigree

Country of Origin

- One-for-One Source exchange is a common industry practice that limits the number of disused sources that may otherwise be abandoned. Practice may be jeopardized if Country of Origin restrictions limit import/export opportunities.
- Some countries are simply unwilling to accept sources that are not considered their country of origin

Challenges – Source Pedigree

Source pedigree barriers are political.

Does it make sense to complicate end of life management practices when a DSRS can be safely and effectively managed by a source manufacturer willing to do so?

Challenges – Transportation

Consider two general aspects associated with the transportation of radioactive sources that must be dealt with when discussing end of life management strategies for DSRS.

(1) Cost and (2) Logistics

Logistical barriers addressed through communication and awareness, may result in Denials & Delays of shipments but that lengthy discussion is for a Steering Committee conference.

Challenges – Transportation

- The cost associated with transferring a new source from the manufacturer to the end user is a significant fraction of the total expense.
- A similar cost would be associated with transporting a disused source back to the manufacturer.
- It is safe to assume that this cost discourages some end users from returning sources to the manufacturer.

Challenges – Transportation

What can we do as Industry and as the Regulatory Authority to address this issue?

- One-for-One exchanges – cost effective way of getting a disused source returned to the manufacturer, reduces overall cost to end user
  - Package, equipment and personnel necessary to support the exchange are already on-site.
  - Instances when a source is contained in a device the end-user has an incentive to return the device with the old source to have the device reloaded.

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Challenges – Transportation

- Limited Supply Chain – On the surface this is a logistical issue but the result is an increase in cost.
  - Limited carriers, routes and containers = limitless costs.
  - Industry and regulatory authorities need to work this issue from both sides. Industry needs to and does work with carriers and ports in an effort to increase their transport options.
  - Regulatory requirements should not be such that they become a barrier to companies willing to enter the transportation industry.

Challenges – Container Availability

Lack of containers does result in an increase in transportation costs but the limited availability has far reaching consequences that introduce additional barriers in the over all scheme of DSRS management.

Challenges – Container Availability

Device Specific Containers:

Many containers where built for a specific device. The Container is no longer certified and/or the manufacturer of the device no longer exists.

The cost associated with developing a container to transport the device is not commercially viable. – What can be done?

Challenges – Container Availability

Device Specific Containers:

Some work has been done, removing the source in the field and leaving the device behind.

Requires a hot cell, expertise and a container authorized to transport the DSRS. Complicated further if the source lost its special form certification.

Challenges – Container Availability

Containers - Authorized Contents:

Most containers dedicated for transporting sealed sources are limited to Special Form.

A good portion of DSRS have lost their special form certification or cannot be identified. – What can be done?

Challenges – Container Availability

Containers - Authorized Contents:

Over encapsulate the source into a special form capsule – hot cell and expertise, this has been done.

or

Develop a source transport container authorized to transport both normal and special form – takes a lot of time and money but a container is expected to be certified for this application before spring.

Challenges – Container Availability

Type B(U) Packages meeting TS-R-1 not accepted for use in other countries:

This not only further limits available containers, it restricts the supply chain.

In some countries a lengthy revalidation process is required for a vessel or aircraft to dock or land on its way to final destination. – What can be done?

Challenges – Container Availability

Type B(U) Packages meeting TS-R-1 not accepted for use in other countries:

US and Canada developed a joint guide for Approval of Type B(U) and Fissile Material Transportation Packages - The guide is designed to facilitate the validation of Competent Authority approvals for export/import purposes and limit redundant technical reviews

This type of cooperation between Competent Authorities is worth expanding.

Challenges – Additional Requirements

- Current regulatory framework is comprehensive and robust. Variations in the application of the requirements that can lead to delays and denials of new sources and could also impact DSRS.
- Additional guidance on the verification of declared content in the transport of nuclear and other radioactive material across borders may further complicate the end of life management of DSRS.
- Guard against the introduction of regulation specific to the movement of DSRS.

Conclusions and Recommendations

- Do not categorize DSRS as radioactive waste by default
- Source users must consider financial costs associated with end of life management of radioactive sources at the time of procurement
- Guard against the introduction of regulation specific to the movement of DSRS
- Harmonize DSRS management expectations - source pedigree, repatriation, original manufacturer vs qualified manufacturer
- Recognize source manufacturer capabilities and limitations, - technological, financial and regulatory
- DISPOSAL – DISPOSAL – DISPOSAL

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