SAFE AND SECURE LIFE CYCLE MANAGEMENT OF RADIOACTIVE SEALED SOURCES

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ABSTRACT

The International Source Suppliers and Producers Association (ISSPA) is comprised of most of the world's major manufacturers of sealed sources. The mission of ISSPA is 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. Radioactive sources are used globally for a wide range of beneficial applications in health care, in industrial exploration and development, as well as in basic scientific research and discovery. In the health care industry, applications include sterilization of medical products, radiation therapy for cancer treatment, nuclear medicine and food irradiation. Other applications, such as oil exploration and industrial radiography make extensive use of radioactive sources. This presentation will elaborate on the extent to which sources are used in some of these applications.

The safe and secure use of radioactive sources in these sectors requires collaboration amongst all key stakeholders that affect the various operational aspects of the supply chain. The list of key stakeholders includes suppliers and producers, users, carriers, and regulators. They are involved during the useful operational life of radioactive sealed sources as well as the appropriate disposition of them at the end of their useful life.

How can safety and security be enhanced during the source life cycle? What measures are suppliers and producers taking to enhance security during source transportation? What are some of the operational impacts that need to be considered when implementing safety and security measures? What is needed to ensure that sources are and can be managed effectively at the end of their useful life? What is the role of key stakeholders in this process? In particular, how important is availability of appropriate infrastructure in providing options to users and suppliers for safe and secure source management? These are topics that will also be covered in the presentation.

INTRODUCTION

ISSPA is an industry association comprised of 15 members who distribute product globally. These companies are engaged in the manufacture, production and supply of sealed radioactive sources and/or equipment that contain sealed radioactive sources as an integral component of the radiation processing or treatment system, device, gauge or camera. As a non-governmental organization, ISSPA and its' members are actively involved with regulators and legislators in developing

regulations and guidelines to enhance source safety and security. Membership and details regarding ISSPA can be found at www.isspa.com.

Radioactive sources are providing significant benefits to all people, whether it is advancements in medical treatment, industrial exploration and safety, agricultural research, or advanced security methods. In fact, radioactive sources are ubiquitous, being found in households, factories, research labs, medical facilities or in mobile vehicles used for exploration in field applications.

Certainly to ensure a robust and thriving radioisotope sector, it is imperative to develop and implement mechanisms to reliably supply radioactive sources and also to ensure the safe management of sources at the end of their useful live. The role of key stakeholders in ensuring overall safety and security of radioactive sources during their life cycle will be discussed.

SIZING THE POTENTIAL FOR RADIOACTIVE SOURCES

The human and commercial value associated with use of radioactive sources is substantial. In medicine, Cobalt-60 sealed sources are used for external beam radiation cancer treatment, with more than 45,000 treatments per day provided in some 50 countries around the world. Brachytherapy, another form of radiotherapy, involves isotopes such as Iodine-125 and Palladium-103 in sealed sources which are placed inside or next to the area or tumor requiring treatment. Radiation processing using Cobalt-60 is an integral manufacturing process in the production of many medical disposable products. Cobalt-60 is used by major health product manufacturers to sterilize some 45% of all single use medical disposables such as sutures, catheters, syringes, heart valves, artificial joints and about 80% of all surgeons' gloves.

Radioactive sources are used in industrial applications and in public safety for checking weld integrity. They are used in radiography for non-destructive testing and assessment of structural integrity of critical infrastructure and equipment, such as bridges, engines, castings, and aircraft. In many industrial facilities, sources are used in process control for such things as level, thickness or density gauging. The oil exploration industry also utilizes radioactive sources, such as Americium-241 Beryllium and Cesium-137, for nuclear or gamma well logging. Sealed sources are utilized in the security industry for detecting explosives, drugs, toxic chemicals or gases; these sources may exist in a fixed setting in the factory or in mobile equipment. Finally, tens of millions of homes and businesses around the world utilize small amounts of radioactivity in smoke detectors and thus are also beneficiaries of the sealed source industry.

There are widely varying estimates of the number of radioactive sources that are currently being used throughout the world. There are millions of smaller radioactive sources containing radioisotopes such as Radium-226, Cesium-137, and Iridium-192 that are used for brachytherapy applications around the world. Industrial gauges containing radioisotopes such as Cobalt-60, Cesium-137, and Americium-241 are widely used around the world in construction and industrial processes. It is generally understood that some 10,000 beam therapy sources are used for cancer treatment, and somewhere in the range of 1,000 to 2,000 sealed sources are contained within self-contained irradiators that are being used to treat blood and prevent the potential for transfusion associated graft vs. host disease. In addition, there are thousands of industrial Cobalt-60 sources being used for the sterilization of medical disposable products and consumer goods. The radioactivity in each source ranges significantly from low quantities in check sources to large

quantities in Cobalt-60 sources used for radiation processing of medical products and food. It should be noted that many of the sources in use contain little radioactivity and therefore are not of any significant radiological risk.

In 2002, an IAEA press release mentioned the IAEA has tabulated that worldwide, there are more than 20,000 operators of significant radioactive sources: more than 10,000 radiotherapy units for medical care are in use; about 12,000 industrial sources for radiography are supplied annually; and about 300 irradiator facilities containing radioactive sources for industrial applications are in operation. The commerce in this important product in the eight years since then has certainly added to the number of licensed users, the transport of radioactive sources and the quantity of sealed sources in field applications.

THE ROLE OF KEY STAKEHOLDERS IN SOURCE LIFE CYCLE MANAGEMENT

The effective life cycle management of sources requires active participation and leadership by all of the key stakeholders. These stakeholders include the IAEA, national competent authorities, suppliers and producers, users and waste management site operators.

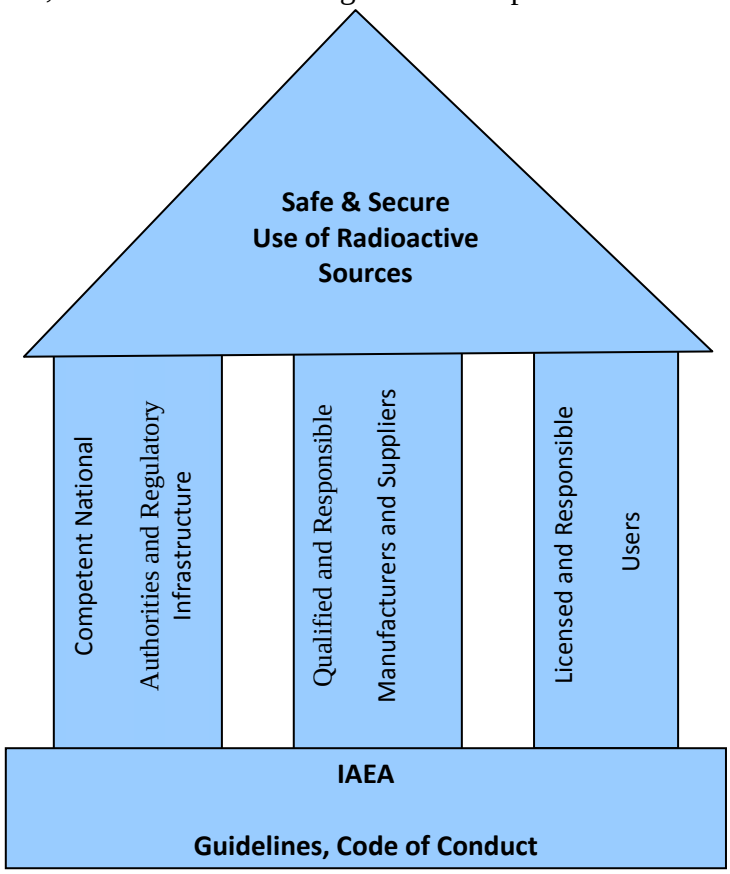

Figure 1: Source Life Cycle Model

The life cycle model that ISSPA members promote is shown schematically in Figure 1. This schematic identifies the key stakeholders that have a strategic role in the industry. These

stakeholders also have operational responsibility in their jurisdictions to establish policies, regulations, infrastructure and operations that are focused on safety and security of sources throughput their life cycle. Each stakeholder must exercise oversight and leadership within their own domain, while recognizing that they are part of a broader structure which requires a strategic approach to ensure the continued beneficial use of radioactive sources.

ISSPA members have adopted this life cycle management model in their business practices for sources that they supply. This life cycle approach encompasses all activities from the safe and effective supply of new sources to the return of disused sealed sources to the supplier or to a secure waste management facility.

As Figure 1 illustrates, the **IAEA** provides the foundation for safety and security of radioactive sources. As an international organization whose charter has been subscribed to by Member States, the IAEA has tremendous capability to develop guidelines and facilitate adoption of these guidelines by the Member States in their national regulations.

As an example, a defining guideline that has been published is the Code of Conduct on the Safety and Security of Radioactive Sources. In support of the broad mandate of the Code of Conduct, in July 2009, the IAEA hosted a Technical Meeting on the **Implementation of the Code of Conduct on the Safety and Security of Radioactive Sources with regard to Long Term Strategies for the Management of Sealed Sources.** One of the objectives of the Technical Meeting was to explore possible strategies related to the management of sealed sources, in particular when these sources are disused, or when orphan sources are detected at borders or during transport. A follow up meeting was organized by the IAEA in May, 2010, entitled **technical and open ended meeting for technical and legal experts for sharing information as to the States' Implementation of the Code of Conduct and its Supplementary Guidance on the Import and Export of Radioactive Sources.** These are key meetings to ensuring effective and consistent implementation of the Code of Conduct.

The **national authorities and agencies** also have a key role to play as they enact regulations controlling use of radioactive sources in their territory. One key area is the availability of licensed shipping containers either to transport a new source to the user, or back to the supplier or a licensed waste management facility at the end of the sources' useful life. In many instances, disused sources are found in remote places where access has been limited or their use has gradually disappeared so that they become forgotten about. Also, with the passage of time, the license on the container that originally transported the source to the user has expired and, for various reasons, is not renewed. A safe and reasonably expeditious mechanism is required to grant a special permit to transport the disused source, and this is a key role for a regulatory agency, or agencies if more than one country is involved.

Users of radioactive sources, for the purpose of this paper, are in two categories, the licensed owner of the source who is using it for radiation applications and the waste management or disposal facility. The licensed owner has a substantial obligation to ensure the source is managed properly during, and at the end of, its' useful life. This will normally require that the owner make some financial provision for end of life disposition, either by returning it to the producer/supplier or sending it to a licensed waste facility. Once the source reaches the end of useful life, the owner

should act in a timely manner to disposition the source as stated above so that the source does not become forgotten about and thus "disused".

Safe and secure source life cycle management requires access to a licensed waste management facility. Unfortunately, these are limited in availability and difficult to use. In many countries, such a facility simply does not exist. In others, the capability is being reduced. For example, in the United States, the closure of the low level radioactive waste disposal site in Barnwell, South Carolina in July 2008 and the unavailability of the Richland, Washington site to out-of-compact waste has increased concerns in the public and private sectors about the security of disused radioactive sealed sources without a disposal pathway. In Canada, there is also limited ability to dispose of radioactive sources. National authorities and agencies must consider the importance of licensed waste facilities in the life cycle management of radioactive sources; it is a key consideration to minimize the risk of a disused source.

As Figure 1 illustrates, the **producer or supplier** is also one of the key stakeholders to ensure the safe management of sources during their life cycle. Sophisticated producers and suppliers take a broad approach to source design, device design, packaging and transportation, and licensing. They consider all design and manufacturing aspects that will impact upon the supply, return, and management of radioactive sources. For example, in 2003, during the early developmental stages of forming an industry association, ISSPA members participated in a Technical Meeting arranged by the IAEA that examined source and device design with the objective of enhancing security and the safe return of disused sources. Many safety enhancements have been incorporated into the design and manufacturing of products through continuous improvement initiatives.

ISSPA members have adopted and abide by a comprehensive and effective Code of Good Practice that encompasses all key aspects of their radioactive source business. This Code of Good Conduct, which can be found on the ISSPA Web site, includes life cycle practices that provide for the return and management of sources at the end of their useful life.

The capability that manufacturers provide to manage sources at the end of their useful life is significant in reducing the occurrence of disused sources. As an example, Gamma Service Recycling GmbH, International Isotopes Inc, MDS Nordion, and QSA Global Inc. are ISSPA members who provide for return of sources and recycle source material. This has the effect of reducing the number of disused sources and the amount of radioactive sources that are required for long term storage.

A COMMENT ON TRANSPORTATION EXPERIENCE

Transportation experience with radioactive sources has shown that, while logistically complex, an impeccable record of safety exists. This is due to the initiatives taken by regulators, suppliers and carriers. These parties recognize the concerns and perceptions associated with safety and security of these vital materials. They apply significant management oversight and operational procedures to ensure products are safely delivered in a timely and expeditious manner.

Suppliers and carriers have worked in compliance with regulatory direction and rules to develop and apply transportation security plans where these are required due to the nature of material being

shipped. In North America, suppliers and carriers have also enrolled in certain governmental programs to facilitate the movement of products across national borders.

Furthermore, to provide a level of safety and security during distribution, packages are routinely tracked and delivery is coordinated with national and local regulatory authorities. In some shipments, package and / or truck tracking technology is employed until the shipment safely reaches its destination.

One of the key detractors from the positive steps that have been taken to enhance transport safety and security is the continuing issue of Denial of Shipments. Denials of shipments or significant delays of transport, either in transit or before transportation occurs, can have the effect of increasing safety and security concerns. If packages containing radioactive material are sitting on the dock, held up in a port, or otherwise delayed in transport, it increases the time at risk during this critical link in the supply chain. And certainly any Denial precludes the availability of the radioactive source to perform the beneficial use for which it was intended.

ISSPA urges all stakeholders in the supply chain to address this issue and work with the IAEA International Steering Committee on Denial of Shipment of Radioactive Materials to accomplish the Action Plan that has been set out by them.

In 2003, the IAEA convened an IAEA International Conference on the Safety of Transport of Radioactive Material. At that conference it was noted that:
"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."

The writer is not aware of any change to this long standing record of accomplishment. May it be the continual goal of all stakeholders to uphold this record of achievement.

RECOMMENDATIONS

A strategic approach to safety, security, and life cycle source management is fundamental to strengthen the long term control of radioactive sources This approach will also foster a robust business in the beneficial use of radioactive sources. It will also minimize the number of disused sources that are posing a risk society. As Figure 1 has shown, there are several key stakeholders involved in various aspects of a source life cycle. Regulators, manufacturers, suppliers and users all have specific, but complementary and overlapping roles and responsibilities to provide for effective life cycle management of radioactive sources.

Some recommendations for each stakeholder to consider are:

IAEA - continue to lead internationally in the development of guidelines that provide for the safe and secure use of radioactive sources during their life cycle. In this regard, consultation with Member States and industry is important to have an effective source management system. Continue to develop the effectiveness and implementation of the Code of Conduct. Provide training in geographic regions that require support to implement the Code of Conduct.

National regulators- develop regulations that are harmonious with international standards. Regulations need to be developed that will support adherence and consistency with the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources. Facilitate the return of disused sources by making special permits available when one is needed to transport an old or disused source for which a licensed container is no longer available.

Owners/users – ensure effective source management policies and operational procedures exist during the useful life of the radioactive source. Have in place operational procedures and financial measures that provide for the disposition of sources at the end of their useful life. Make arrangements for appropriate disposition of the source in a timely manner.

Waste Facility operators/agencies - ensure a capability exists for the safe and cost effective management of sources at the end of their useful life.

Producers/suppliers - participate with the IAEA and National regulators in developing guidelines, regulations and practices that enhance the safety and security of radioactive sources. Adhere to the management practices outlined in the ISSPA Code of Good Practice. Strive for continuous improvement in all of these practices that you have adopted to ensure products and services reflect the current perceptions about safety and security.

CONCLUSION

Sealed radioactive sources provide many benefits to society in medical research and therapy applications, sterilization of medical products, food irradiation, industrial safety and security. They are integrated into daily aspects of life and are a key component to providing economic growth. And, as with many technologies, it is important to consider the full life cycle of this product to ensure that societal risks from use of sources is minimized. In this regard, the importance of an effective life cycle management is imperative to the safety and security of radioactive sources. A multi-faceted approach to sealed source life cycle management between manufacturers/distributors, shippers, customers/users is imperative to ensure that sealed sources are available to the benefit of mankind for generations to come.