The Role of a Supplier in the Safe and Secure Management of Disused Radioactive Sealed Sources-10356

G. Malkoske, International Source Suppliers and Producers Association (ISSPA)
447 March Road, Ottawa, Ontario, Canada K2K 1X8
W. Fasten, Eckert & Ziegler Nuclitec GmbH, Gieselweg D-38001 Braunschweig, Germany
J. Miller, International Isotopes Inc., 4137 Commerce Circle, Idaho Falls, ID 83401

ABSTRACT

Radioactive sources are used worldwide for a wide range of beneficial applications in the health care industry, in industrial exploration and development, as well as for basic scientific research and discovery. In fact, some 45% of the world's medical disposable products are gamma sterilized using Cobalt-60 in processing plants located around the globe. Other vital applications, such as cancer treatment, nuclear medicine, oil exploration and industrial radiography make extensive use of radioactive sources.

The safe and secure use of radioactive sources in these sectors requires collaboration between suppliers and producers, users, and regulators during the useful life of radioactive sources as well as the appropriate disposition of sealed sources at the end of their useful life. However, in some cases, lack of management oversight of disused sources has raised concerns about their safety and security. What are some examples whereby lack of management oversight has created concerns about disposition of disused sources? What can we learn from these examples? 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 initiative? In particular, what are suppliers and producers doing to manage spent and disused sources at the end of their useful life? How important is availability of disposal infrastructure in providing options to users and suppliers for safe and secure source management?

This paper will discuss the above and will provide some examples to show how members of the International Source Suppliers and Producers Association have been actively addressing some of these issues.

INTRODUCTION

The International Source Suppliers and Producers Association (ISSPA) is an industry association comprised of 15 international member companies that 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. Membership and details regarding ISSPA can be found at www.isspa.com. As a non-governmental organization, ISSPA and its' members are actively involved with regulators and legislators in developing regulations and guidelines to enhance source security. Individual members, licensed by their local competent authority, are also involved in the implementation of regulations and rules to enhance source security.

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.

Reports from industry [1] and researchers [2] has shown that the human and commercial value of these uses 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, and in radiography and non-destructive testing for assessment of structural integrity of critical infrastructure and equipment including 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.

However to ensure a robust and thriving radioisotope sector, it is imperative to develop and implement mechanisms to not only reliably supply radioactive sources, but also to ensure the management of sources at the end of their useful live.

SIZING THE POTENTIAL QUANTITY OF DISUSED SOURCES

There are widely varying estimates of the number of radioactive sources that are currently being used throughout the world. Previous reports [3] have stated there are millions of smaller radioactive sources containing radioisotopes such as Radium-226, Cesium-137, and Iridium-192 used for brachytherapy applications that exist throughout the world. Others with a relatively low content of radioisotopes such as Cobalt-60, Cesium-137, and Americium-241 are used in industrial gauges. 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 (thousands of curies) 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 [4] 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.

In the United States, *The Interagency Radiation Source Protection and Security Task Force's 2006 Report to Congress and the President* provided a perspective that helps to size the potential quantity of sources that might become disused. It noted [5] that "holding a source in storage longer than 24 months usually indicates the lack of a strategy to use or dispose of the source." The significant majority of the sources mentioned above are used routinely in processing facilities, hospitals, and clinics or in daily field operations, and therefore would not fall into the disused category.

However, the quantity of radioactivity in many of the sources, particularly those in those referred to as Category 1, 2, or 3 makes it imperative to provide an infrastructure capability for management of disused sources to minimize the quantity. The capability includes items such as knowledgeable people, licensed shipping containers, transportation, and a licensed waste management facility. It also includes the ability to obtain, in a timely manner, a special permit if the license on an old model of container has expired.

The IAEA has written publications that report on incidents involving disused or orphan sources and the consequences of them. For example, incidents in Goiana, Brazil (1987) [6], China (1992) [7], Thailand (2000) [8] and Egypt (2000) [7] have resulted in the deaths of twelve individuals. During the period of 1983-1998, it is reported that there were 59 incidents of major contamination involving sources lost in the metal recycling industry [7] In February 2009 the IAEA reported [9] that "In the last three years the IAEA has become aware of about 500 events involving uncontrolled ionizing radiation sources, about 150 of which were related to sopurces found in scrap metal or contaminated goods or materials". Other incidents reported upon [7,10] in Georgia (1997), Turkey (1998) and Peru (1999) resulted in serious radiation overexposure to a number of individuals. All of these situations accentuate the need for effective management of disused sources.

THE ROLE OF KEY STAKEHOLDERS IN MANAGING DISUSED SOURCES

The effective management and control of disused 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. All of these key stakeholders must be actively engaged in the life cycle management of radioactive sources.

The life cycle model that ISSPA members promote is shown schematically in Figure 1. This schematic does not illustrate the operational steps that are necessary in managing the life cycle of a source. Rather it identifies the key stakeholders that 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 more holistic approach to ensure the continued beneficial use of radioactive sources.

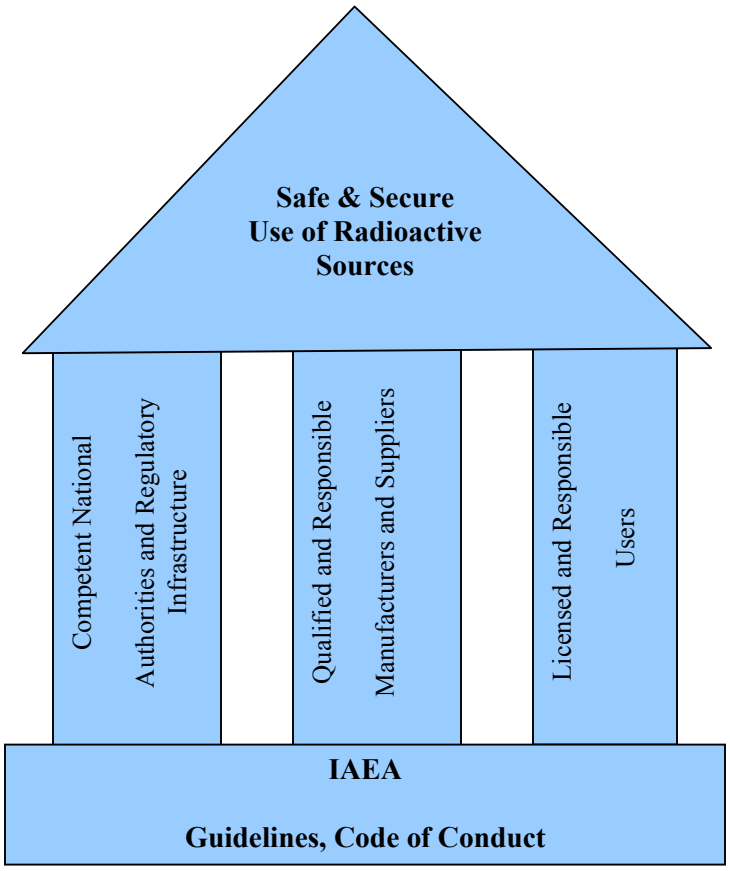

Figure 1: Source Life Cycle Model

ISSPA members have adopted a life cycle management approach to sources that they supply. This life cycle approach includes the safe and effective 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 facilitation capability to develop guidelines that are subscribed to by the Member States and adopted, in principle, in whole or in part, in national regulations.

Along this line of discussion, a defining guideline that has been recently published is the Code of Conduct. 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** [11]**.** 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. The Chair paper noted that the long-term management of disused sources is of wide concern to all Member States. The Chair paper also highlighted some of the possible causes for orphan sources and referred to some key elements for the management of disused sources, for example the availability of licensed and secure waste management sites.

The national authorities and agencies also have a key role to play by virtue of the regulations that are enacted as well as the facility capability that is provided for management of disused sources. One key area is the availability of shipping containers to transport a disused source either back to the supplier or to a licensed waste management facility. 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. 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 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.

Also, a necessary part of facility capability is availability of 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. There are relatively few states that provide for the disposal of radioactive sources. 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 event 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 at the end of their useful life. Interestingly, one might consider it important only to focus on the return of disused sources - items such as packaging, licensing and transportation. However, it should be recognized that a holistic approach to source design, device

design, packaging and transportation, and of course licensing, is necessary. Sophisticated producers and suppliers take such a broad approach to cover all aspects that will logistically impact upon the return and management of disused sources. To this extent, ISSPA members, in 2003 during the early developmental stages of forming an industry association, participated in a Technical Meeting[12] arranged by the IAEA that examined source and device design with the objective of enhancing security and the safe return of disused sources.

The philosophy of ISSPA members is to abide by a comprehensive and effective Code of Good Practice that incorporates the return of sources that a producer will supply. This Code of Good Conduct includes life cycle practices that provide for the return and management of sources at the end of their useful life. The Code of Good Practice includes:

- Regulatory Compliance – which requires members to comply with all applicable requirements, participate in the development, interpretation and implementation of regulations and guidelines
- Quality Management – consistently apply quality management to all aspects of source an equipment life cycle that is under the manufacturers' or suppliers' control, and perform all appropriate investigation and follow-up actions required to safety or security events
- Design of sources and devices – including physical features or properties to limit vulnerability to illicit use and labeling for tracking purposes
- Manufacturing – maintain safety and security of materials during the isotope delivery and source manufacturing cycle
- Sales – know the customer, verify legitimacy of customers and their authorization to possess the sealed source
- Distribution – maintain safety band security during transit and verify timely receipt at the intended destination
- Tracking – maintain key information for source tracking purposes, and make this information available as required to regulators
- After-sales Support – provide operating, handling and maintenance instructions that include safety and security information
- End-of-Life Source Management – assist the user where required with managing disused sources via such means as return to manufacturer, recycling, disposal, or identifying financial provision options for managing disused sources

The End-of-Life Source Management capability that manufacturers provide is significant in reducing the advent of disused sources. As an example, Gamma Service Recycling GmbH, International Isotopes Inc, MDS Nordion, and QSA Global Inc. 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 disposal.

RECOMMENDATIONS

Life cycle source management is fundamental to strengthen the long term control of radioactive sources and minimize the number of disused sources that are posing a risk society and to the ongoing beneficial of this important product. As Figure 1 has shown, there are key stakeholders involved in various aspects of a source life cycle to provide for effective management of disused

sources and to mitigate event consequences. Regulators, manufacturers, suppliers and users all have specific, but complementary and overlapping roles and responsibilities.

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.

National regulators - 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. Develop regulations that are harmonious with international standards.

Owners/users - 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 minimize the number of disused sources that might be in the field. Adhere to the management practices outlined in the ISSPA Code of Good Practice.

Regulations need to be developed and implemented by all IAEA Member States to support adherence and consistency with the Code of Conduct and the Guidance on the Import and Export of Radioactive Sources. Competent authorities need to also have regulations or practices in place to recover and deal with orphan sources.

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 disused sources is minimized. In this regard, the importance of an effective life cycle management is imperative to the safety and security of these sources. A multi-faceted approach to sealed source life cycle management between manufacturers/distributors, shippers, customers/users, and those involved in disposition of disused sources is critical. The recommendations contained in this paper for the key stakeholders are considered to be imperative to ensure that sealed sources are able to be effectively utilized to the benefit of mankind for generations to come.

References:

1. A Profile of the Radiation Source Sector. A presentation to the National Academies Committee on Radiation Source Use and Replacement. G. Malkoske, July 2006.
2. Radiation Source Use and Replacement. Report by the National Academies, 2008.
3. IAEA Bulletin 43/4/2001.
4. IAEA Press Release 2002/09 “Inadequate Control of World’s Radioactive Sources”. June 24, 2002.
5. Section 7.3.12, p 83.
6. The Radiological Incident in Goiana, Brazil. IAEA 1988.
7. Radiation, People and the Environment. IAEA, p66, 67.
8. The Radiological Incident in Samut Prakarn, Thailand. IAEA 2002.
9. IAEA Staff Report “Scrapping the Risks, Promoting the Trade”. February 23, 2009
10. IAEA Fact Sheet “Inadequate Control of the World’s Radioactive Sources”.
11. IAEA TM-37003 “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”. July, 2009.
12. IAEA TM-26266 “To Enhance the Safe and Secure Design, Manufacture, Distribution, and Return of radioactive Sources and Devices”, April, 2003.