An Industry Approach to Sealed Source Management at the End of Useful Life – 8440

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ABSTRACT

Radioactive sources provide significant benefits which enhance the general welfare of mankind. These beneficial applications include medical treatment, sterilization of single use medical devices, food safety and agriculture, as well as industrial safety and exploration. The radioisotope sector is broad, diverse, and well established, with a culture of safety and security.

ISSPA's mission 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.

A key consideration of a vibrant safety and security culture is the comprehensive life cycle management of radioactive sources which ensures effective control throughout their life span. Closely linked to this is the commitment by responsible suppliers to take back radioactive sources at the end of their useful life. This is an essential obligation of ISSPA members, as stated in the framework for the ISSPA Code of Good Practice.

This presentation will discuss the above topics and will provide some examples which demonstrate how ISSPA members have effectively managed sources at the end of their useful life.

OVERVIEW OF THE RADIOISOTOPE SECTOR

Radioactive sealed sources significantly benefit a widely varied set of applications around the world. The effective control and disposition of these sources at the end of their useful life is integral to ensuring this growing market continues to be safely and securely managed.

The breadth of applications, locations of use, source size, and type of radioisotope used, all impact the options available for end of life management. This paper will overview the industry, the considerations needed to ensure a strong safety and security culture exists, methods and processes required for end of life management, and finally, recommendations based on lessons learned over the lengthy history of sealed source production and use.

We are all impacted in some way by the peaceful uses of radioactive sources. Such sources have practical applications in medicine, industry, agriculture, food safety, security and in common consumer products. They are found in factories, universities, research centres, hospitals, irradiation facilities, construction sites, oil fields, and even in our homes.

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. In addition, Brachytherapy, which is another form of radiotherapy, involves other isotopes in sealed sources being placed inside or next to the area or tumour requiring treatment. Further, Cobalt-60 is used to sterilize, in production irradiation facilities, some 45% of all single use medical disposables such as sutures, catheters, syringes, heart valves, artificial joints and some 80% of all surgeons' gloves. In fact, some products used in medical procedures, such as biological materials for transplant, alcohol swabs and sealed devices used in endoscopes, can only be sterilized using Cobalt-60. In addition, a multitude of consumer products are also irradiated to assure their safety and sterility, including contact lenses, solutions, bandages, cosmetics, and a variety of health and personal hygiene products. Finally, this critical radioisotope is used in sterilizing lab ware required in drug discovery applications, and in the food industry for preservation of food or sterilization of food packaging materials.

Radioactive sources are used in industrial applications and in public safety for the checking of 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. Further, moisture measurement in soil is critically important in the planning and construction of buildings or such infrastructure projects as highways or bridges, and in oil well logging, and chemical or petrochemical refineries. Finally, 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. In addition, tens of millions of homes and businesses around the world which utilize smoke detectors are also beneficiaries of the sealed source industry.

A number of the more significant companies involved in sealed source production and sale have formed an industry association called "The International Source Suppliers and Producers Association" (ISSPA). ISSPA is international with membership representing the full breadth of the industry. Membership and details regarding ISSPA can be found at www.isspa-org.com.

SAFETY AND SECURITY CULTURE

It is incumbent on industry to ensure the safe and secure use of sealed sources. This includes everything from source production through to final disposition. 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."

The highly regulated environment in which this industry operates provides part of the solution, essentially the foundation, for safe and secure source life cycle management. These regulations govern source production, transportation, sale, possession and use but may vary from one country to another. It is industry's responsibility to work with regulators and their entire supply chain to ensure sealed sources are managed in a manner which affords effective safety and security to users, the public and the environment at all times.

Millions of small radioactive sources such as Radium-226, Caesium-137, and Iridium-192 exist throughout the world. Estimates also indicate that, globally, there are some 10,000 beam therapy sources used for cancer treatment, and that 1,000 – 2,000 sealed sources are present in self-contained irradiators 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.

ISSPA and its members have developed and abide by a comprehensive and effective framework for a Code of Good Practice which will be reviewed later in this paper. Not all source manufacturers, however, are members of ISSPA and may not therefore follow the same practices as defined in this Code.

While industry has a strong and generally effective system of practices and controls in place, 100% uniformity and control of sealed sources does not fully exist. Factors such as the broad geographical distribution of source producers, the varying standards applied to source manufacture and management, the geographical and evolutionary differences in regulation development, and effective life cycle management, can all contribute to this situation. It is therefore the responsibility of purchasers and users of radioactive sealed sources to practice good due diligence in ensuring they are purchasing and managing their sealed source supply from reputable suppliers who will also be able to provide good end of life disposition options. The responsibility, ultimately, rests with the purchasers and users of these sources.

Life Cycle

A high level overview of the requirements for effective life cycle management of sealed sources is depicted in the schematic below. Strong international guidelines provide an effective foundation for consistent regulations, educated and compliant manufacturers and users, and practices which assure sealed sources are used in a safe and secure manner.

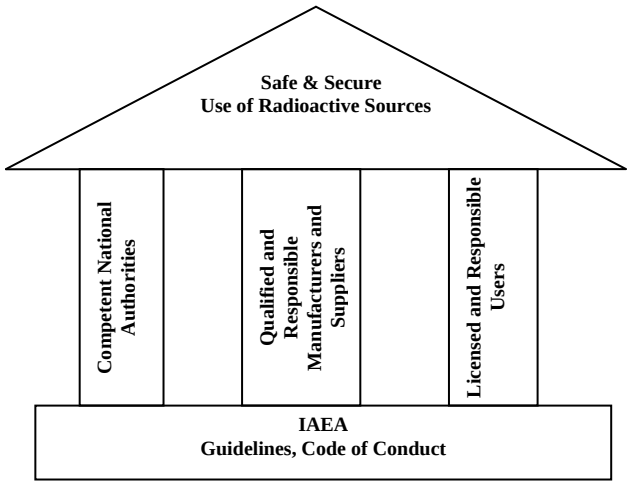

Figure 1: IAEA Guidelines, Code of Conduct

From a more specific perspective, and consistent to all aspects of the industry, is the initial part of the source life cycle:

> *Raw Material → Source Manufacture → Packaging & Transportation → Device Manufacturer/Distributor or Source User*

What is inconsistent is the next phase of the life cycle where sources being replaced or equipment decommissioned are sent for disposition. In an effective and mature environment, the next phase would typically follow the path:

> *Source User → Packaging and Transportation of Disused Source → Source / Device Manufacturer or Distributor / Reputable Source Recycler → Source Recovery through Recycling or Re- encapsulation for Re-use / Source Disposal in Interim / Permanent Disposal Sites*

The point of variation between effective and ineffective life cycle management is the highlighted section above. Disused sources may not be returned to the original manufacturer or distributor or to a reputable recycler, but rather, may either be left abandoned, creating "orphan" sources, or sent to organizations that ineffectively manage the sources through improper recycling or disposal. Proper management of sealed sources is therefore required to ensure full and effective control over the entire life cycle.

Regulatory Environment

The International Atomic Energy Agency (IAEA) has addressed safety and security of radiation sources in several documents, including "International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115 (BSS)" and others in the Safety Reports and TECDOC series.

While such standards have provided good guidance and resultant control of radiation sources, and is adhered to in the vast majority of Member States, there have been a number of serious radiological accidents and incidents involving uncontrolled or orphan sources in several regions of the world. The IAEA determines an orphaned source to be one which is not under regulatory control or has been abandoned, misplaced, lost, stolen, or transferred without appropriate authorization. A source which is "vulnerable" is one over which controls are weak, and could therefore easily become orphaned. Whether orphaned or vulnerable, these sources need to become better controlled, or risk being used in a manner which could adversely affect people or the environment.

Two relatively recent guidelines established by the IAEA are working to assure proper life cycle management of high activity sources. These are the "Code of Conduct on the Safety and Security of Radioactive Sources", and the "Guidance on the Import and Export of Radioactive Sources". While the IAEA has no set dates for formal implementation of these controls, a large number of countries have either implemented or are in the process of implementing these guidelines. Unfortunately, at this time, there is no harmonized implementation process. This creates a situation where varying standards and practices exist throughout the world.

Within the import / export control measures, sealed source manufacturers are required to apply for and receive an Export Licence from their Competent Authority prior to exporting high activity Category 1 and 2 sealed sources to their customer. This licence is only provided once the Competent Authority for the customer authorizes the import of the sources. This process links directly to the customer's facility or site licence, governed by the Member State's Competent Authority, and which ensures the necessary practices, procedures, and processes are in place to safely and securely manage the sealed sources. Seven days prior to the export, notification is provided to the Competent Authority of both the supplier and the customer.

In addition, many Competent Authorities have established Source Tracking Database Systems for Category 1 and 2 sources listed in the Code of Conduct. Companies are required to provide notification to their Competent Authority of the transfer or export of sealed sources and of receipt (transfer or import) of sealed sources. The information required in the notification, which can be submitted electronically or in hard copy format, includes:

- Date of transfer/export/receipt of import
- Name and address of recipient and site (possession) licence number
- Name and address of sender and licence number
- Radionuclide and activity on a specific reference date
- Number of sealed sources and total activity
- Serial number of the sealed source(s) and corresponding equipment, if applicable

The link between manufacturer and manufacturer's Competent Authority (Export Licence), customer and customer's Competent Authority (Import Licence) and the customer's Site or Operating Licence, helps significantly to ensure that control over the sealed sources exists throughout the source life cycle. The key to maximizing the effectiveness of these practices is ensuring that ALL Member States implement and abide by these international controls and practices.

MANAGING SOURCES AT THE END OF THEIR USEFUL LIFE

The ISSPA Code of Good Practice, if followed universally, would significantly help to ensure a global safe and secure use, transportation and disposal of sealed sources.

Key points from the Code of Good Practice which contribute to good life cycle management include:

- Quality Management – consistently apply quality management to all aspects of source an equipment life cycle that are under the manufacturers' or suppliers' control, and, perform all appropriate investigation and follow-up actions required to safety or security events
- 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

Many manufacturer's of sealed sources offer a guaranteed return policy where, at the time of purchase, warrant that they will accept the return of the sealed source at the end of its useful life. The costs for return and disposal are the responsibility of the customer. However, this provision ensures that the full life cycle of the source will be properly managed and that customers will not be solely left to find a means of disposal.

Reputable manufacturers of sealed sources such as MDS Nordion utilize varying methods for end-of-life source management. Disposal at a licenced facility is one route but this is expensive and utilizes long term space at such a facility. Utilizing recycling of sources provides a win:win:win scenario – a win for the customer who can readily return the sources whenever they wish; a win for the environment since no space is occupied by disposed of sources; and a win for the manufacturer who is able to optimize source utilization.

Some manufacturers place a significant emphasis on source re-cycling, with MDS Nordion, for example, re-cycling approximately 90% of the Cobalt-60 sealed sources used in production irradiation and cancer treatment applications. In the same manner, QSA recycles some 80% of the Kr-85 used in gauging systems.

Although to a much lesser extent, some sources used in self-contained irradiators are also recycled. Where such an option does not exist, disposal at a licenced facility occurs. Such a facility must meet all requirements as established by the regulatory authorities having

jurisdiction. Because disposal means a transfer of sources, the notification and source tracking actions occur, thus closing the loop on the source's life cycle. For all sources, whether recycled or sent for disposal, MDS Nordion uses a source tracking program to log and maintain complete records on all sources produced.

It is important to recognize that such diligent practices and controls are needed to maintain safety and security of sealed sources. These controls will help to mitigate the potential for ineffective source management. This further applies to the purchaser or user of the sealed source, to ensure that they maintain records of disposition, and thus ensure traceability is maintained.

Where such controls do not exist, and if disposition were to a location or company which does not effectively monitor, record or handle sealed sources, a situation can quickly arise where the level of needed control is lost.

In another example, a situation may exist where a source user abandons a site and the sources remain behind. This is an industry issue which is being addressed by various means – from the customer posting a financial guarantee at the time of purchase which will assure effective disposition of the sources at end of useful life, to the worst case scenario where the IAEA/regulator /other Agency steps in, assumes control of the sources, and works to formally dispose of them in a proper manner. Some ISSPA members have been involved in working with the IAEA in retrieving orphaned sources and moving them to safe disposal.

RECOMMENDATIONS

Life cycle source management is a cornerstone to strengthening the long term control of radioactive sources. An integrated, system approach to source/equipment security is necessary for effective management of disused sources and to mitigate event consequences. A risk-informed approach is fundamental to ensuring the effective security of sources and devices. Regulators, manufacturers, suppliers and users all have specific, but complementary and overlapping roles and responsibilities.

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.

Using these regulations as a baseline, manufacturers, distributors, users, transportation companies, disposal sites and reprocessors must work to standards, such as those identified within the ISSPA Code of Good Practice, which contribute to enhancing safety and security of sources throughout their life cycle. Users of sealed sources need to ensure they are dealing with reputable suppliers and that those suppliers will support them at the end of the source's useful life.

CONCLUSION

Sealed radioactive sources play a major and very important role in global industry and health. Their applications are varied and they are produced and shipped in the thousands each year around the world. 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 IAEA Code of Conduct, from a regulatory perspective, and the ISSPA Code of Good Practice, from an industry perspective, will help to ensure that sealed sources are able to be effectively utilized to the benefit of mankind for generations to come.