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Denial of Shipment of Radioactive Materials

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ABSTRACT

The International Source Suppliers and Producers Association (ISSPA) comprise most of the world's major manufacturers of sealed sources. In 2009 and 2010, the author was Chairman of the IAEA International Steering Committee (ISC) on the Denial of Shipment of Radioactive Material, and since that time has continued to actively participate on the ISC management team.

We are all impacted by the peaceful uses of radioactive material. Currently, more than 35 million nuclear medicine procedures are performed annually around the world using short lived radioisotopes. Cobalt-60 sealed sources are used for external beam radiation cancer treatment with more than 45,000 treatments per day in some 50 countries globally. In addition, Cobalt-60 sterilizes some 45% of all single use medical disposable products, and in the food industry preserves food and sterilizes food packaging materials. Further, radioactive sources are used in industrial applications to check weld and structural integrity; in industrial facilities for process control; in drug discovery; and in numerous other industrial, agricultural and home applications.

Use of these products is dependent upon safe, secure, timely and cost efficient transportation both within and between countries. Delay or denial of these shipments has a direct and potentially serious and life threatening impact on industry, on health care and on individuals around the world. Reported denials now number in the hundreds with several hundred more identified but not formally reported. This issue was discussed at PATRAM 2010. What has happened in the interim? Where and why are these denials still occurring? What are international agencies, regulators and industry doing? What impact are these actions having in mitigating or resolving denials? The IAEA had a target of reducing denials to an "insignificant level" by 2013. What is the status of this target? Further, the structure of the Steering Committee is changing significantly - what are these changes and will they have a positive or negative impact on the work completed to date or now underway? This presentation will answer these questions and more, and will provide industry perspectives on how the issues causing denial of shipment can be addressed.

INTRODUCTION

Radioactive materials are key to a wide variety of applications globally and have been broadly and extensively used for decades. Their use continues to grow. It is therefore critical that we ensure the ongoing safety and security of the transportation and use of these products.

As with many critical use products, a wide variety of radioactive materials and in particular short lived radioisotopes and radiopharmaceuticals and many sealed sources require reliable, fast and efficient transport from supplier to end user. Inability to provide reliable, cost and time efficient transport will have a deleterious effect, not only on the industry supplying the product, but even more importantly, on the industry or the public that uses and relies on these

products. Since radioactive materials are always decaying, the need for an effective global transportation process is imperative.

USES AND APPLICATIONS OF RADIOACTIVE MATERIALS

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

In medicine, some 35 million nuclear medicine procedures are performed annually using a variety of radioisotopes and radiopharmaceuticals; cobalt-60 sealed soruces 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, which is another form of radiotherapy, involves other isotopes in sealed sources being placed inside or next to the area or tumour requiring treatment; and nuclear medicine products and radiopharmaceuticals are used millions of times per year in the diagnosis and treatment of a multitude of diseases. Further, Cobalt-60 is used to sterilize ~45% of all single use medical disposables such as sutures, catheters, syringes, heart valves, artificial joints and ~80% of all surgeons' gloves. In fact, some specific 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.

Radioactive sources have routine use 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, sealed sources are used in process control for such things as level, thickness or density gauging. Further, moisture measurement in soil is crtically important in the planning and construction of buildings and in such infrastructure projects as highways or bridges, and in oil well logging, and chemical or petrochemical refineries. Finally, sealed sources are routinely used 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 transported to the point of use. In addition, tens of millions of homes and businesses around the world which incorporate smoke detectors as part of their safety and security programs are also beneficiaries of the sealed source industry.

The International Source Suppliers and Producers Association (ISSPA) is an industry association, founded in 2005, and comprised of 16 international member companies from 9 countries, that are engaged in the manufacture, production and supply of radioactive sealed sources and/or equipment that contain radioactive sealed sources as an integral component of the radiation processing or treatment system, device, gauge or camera. ISSPA provides a global voice for the industry and is a recognized Non-Government Organization (NGO) of the IAEA. It actively participates as a member of many IAEA Technical Meetings, Consultancies, Working Groups, conferences, Standards Committees, Nuclear Security Guidance Committee (NSGC), and Steering Committees. This participation helps provide a practical and global approach to the development, implementation and application of international guidelines and ultimately national regulations with respect to the safety and security of radioactive sealed sources. In addition, ISSPA participates in other UN/international organizations (IMO, ICAO, IATA), national, as well as local meetings where issues impacting and impacted by sealed sources are in review. Membership and details regarding ISSPA can be found at www.isspa.com.

HOW IS SAFETY AND SECURITY IN TRANSPORT MAINTAINED

Shipments of radioactive material occur daily by all modes of transport through a wide variety of carriers, and through air, ocean, road, and border Ports globally. The vast majority of all

these movements occur routinely, on time and without issue. The transportation of radioactive materials is highly regulated at the international level through three United Nations (UN) organizations: the International Atomic Energy Agency (IAEA), International Martime Organization (IMO) and International Civil Aviation Organization ((ICAO). Based on these international standards, regulations are promulgated and applied at the national level by such competent authorities as a country's nuclear or transport regulator. Further, state, provincial, municipal or local regulations may separately or jointly govern the movement of these products around the world. Finally, Ports (air, land border or sea) through which these products pass will also institute controls to which these products, in transport, must abide. The level of control and the regulations to which radioactive sealed sources must adhere is therefore highly specific and highly integrated.

Since September 11, 2001, these regulations, which primarily focused on safety, have been supplemented with globally instituted security enhancements. For example, the IAEA published its "Code of conduct on the safety and security of radioactive sealed sources" (IAEA, 2004), which urged all Member States of the IAEA to follow the guidance contained in the Code and to make a political commitment to the Code. A key objective of the Code was to assist countries in their development, harmonization and implementation of national policies, laws and regulations to achieve and maintain a high level of safety and security of radioactive sources; prevent unauthorized access or damage, loss, theft or unauthorized transfer of sources; and to mitigate or minimize the radiological consequences of any accident or malicious act involving such sources. In addition, the IAEA published "Security in the transport of radioactive material" in the "IAEA nuclear security series no. 9" in 2008. The objective of this guide is to assist Member States in implementing, maintaining and enhancing a nuclear security regime to protect radioactive materials, while in transport, against theft, sabotage, or other malicious acts that could, if successful, have unacceptable radiological consequences. Further, at a national level, countries have implemented regulations which mandate the development and implementation by shippers and carriers, of transportation security plans and programs; personnel security checks; and in the US, specific requirements via safeguarded information; and significant administrative controls applied to or proposed to be applied to the vast majority of radioactive material shipments – both sources and nuclear medicine products.

Radioactive materials shipped by air are typically restricted to products having lower activity while shipments of high activity are shipped by road, rail and sea. While all radioactive material is shipped in accordance with transportation security and safety regulations, the greater the activity of the shipment, the more specific and stringent the regulatory requirements applicable.

Further, given that industry is shipping radioactive materials throughout the world on both cargo and passenger conveyances, or in the courier network, controls on the containers used to carry these products are highly specific and also highly regulated. The containers used to carry radioactive materials can be segregated into two categories: Type A for small activity shipments and Type B for larger activity shipments. Regulatory controls exist for the testing, safety analysis report completion and review, and licensing/registration of these containers, before their availability for use.

Given the highly and tightly controlled environment in which the processing, preparation, shipment and use of these radioactive products occurs, it is easy to see how the IAEA stated (IAEA International Conference on "The safety of transport or radioactive material", 2003) 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". This quote is still valid today. When conducted in compliance with the existing regulatory framework, the transport of these products, undeniably critical to society and important to the global economy, is extremely safe and secure.

ISSUES IMPACTING INDUSTRY

Controls in place to assure safety and security of radioactive materials in use and in transport have had and continue to promote exemplary performance. This does not, however, automatically mean that there are no issues for the industry. Industry is facing distribution challenges in various parts of the world. These are related to concerns about radiation, increased regulatory burden associated with tracking, security and financial surety exacerbated by competing/conflicting regulations, regulatory agencies and regulators. Further, the long standing issue of denials of shipment continue in several regions of the world.

There are instances when, even though all regulatory controls and requirements are met, the regulator, the Port, the carrier, or the handlers, etc. refuse to carry radioactive material or allow it into or through their jurisdiction. In fact, the IAEA defines denial of shipment as "a refusal to carry or allow a shipment of radioactive material though it conforms to all applicable regulations". In other words, from a regulatory safety and security perspective, failure to comply with all relevant international and national regulations CANNOT lead to denial reporting/notification.

Denials of shipment are significant, affecting the public and industry alike - specifically suppliers, consumers, industry, government, construction, patients, hospitals, carriers and all others impacted by the inability to effectively ship or receive, and ultimately, use these products. In addition, the other end of the life cycle is also adversely affected, since denials will adversely impact the ability to transport the spent or expired sources back to the manufacturer or to the waste disposal site for final disposition.

Although denials are occurring globally, they tend to be concentrated in specific geographies, based on origin of supply, supply chain accessibility and capability, available routings to customer sites, and type of source being moved. The ability to predict where and when denials will occur is difficult since changes which lead to denials are random and vary from one geographical area to another and from one time to another. The current global economy and increased security environment in which we live and work are additional factors which preclude our ability to determine when or where denials may occur.

WHAT IS CAUSING DENIALS?

The IAEA, with IMO, and ICAO have conducted significant research into the cause of denials and have identified five reasons:

(i) Negative perception about radiation due to lack of awareness and information about the industry

(ii) Concerns about the cost and extent of training required of those who handle radioactive materials

(iii) Multiplicity and diversity of regulations governing the handling, use and transport of these products

(iv) Lack of harmonization between governments of these regulations which should be international and consistently applied. The end result of reasons (iii) and (iv) is that there are duplicate, overlapping and sometimes contradictory regulatory requirements

(v) Lack of outreach and lack of public awareness about the needs and applications of radioactive materials.

WHAT IS BEING DONE?

Significant effort and actions have been underway since 2006 to deal with denials, spearheaded by the IAEA's International Steering Committee on the Denial of Shipment of Radioactive Materials (ISC). The eighth and final meeting of the ISC, under the IAEA, was held in June 2013. It is now transitioning to the Inter-Agency Group (IAEA, IMO, ICAO,

UNECE and WHO) where a Denials Working Group comprised primarily of past ISC Chairmen and of some IAEA TRANSSC members will promote and continue the efforts to mitigate denials. A close integration with TRANSSC will be maintained to push new and additional efforts forward. Some of the initiatives to support the ongoing ISC Action Plan include:

Awareness:

- Denials database development, trend identification and communication to industry globally via National Focal Points (NFP) and Member States (to ensure magnitude of denials and examples are fully understood)
- Developed a website for providing information required for submitting denial reports
- Established a data base of national and local competent authorities.

Training:

- Developed an e-learning package for Class 7 Dangerous Goods
- Developed an instructional video which overviews the uses and shipping requirements of radioactive material, the regulatory and safety requirements for transporting such material, and the safety record of such carriage
- Participation at conferences and opportunities to communicate denial issues with organizations and conferences globally

Communication:

- Developed Fact Sheets for key radioactive materials in commerce
- Worked with manufacturers to educate them on the denials issue and gain their involvement and participation

Lobbying:

- Attending and articulating the denial issue in other UN organizations' meetings to "de-mystify" the use and transport of radioactive materials and to discuss issue and impact of denials
- Identified stakeholders who are key to the sustainability of radioactive material transport
- Developed an outreach program which will positively influence and educate stakeholders
- Held regional meetings involving all stakeholders

Economic:

- Identified typical costs incurred in the shipment of radioactive materials and comparison against other dangerous goods in transport
- Identified administrative burdens and how they impinge on sustainability, specifically regarding impact on those denying shipment
- Determined administrative changes that would provide a more balanced view of Class 7

Harmonization:

- Identifying all regulations globally that impact transport of radioactive materials, analyse for inconsistencies
- NFP and Regional Network initiatives
- Examined interface and overlap between regulations
- Proposed methodology for reduction of overlaps between regulations

Support of the ISC Action Plan was provided as an outcome of the 2011 Conference on the Safe Transport of Radioactive Material. Arising from this meeting, the IAEA identified eight specific areas of focus for future work by the Agency. These include harmonization; denial of shipment; regulatory development process; safety requirements and security recommendations; Member State implementation and industry compliance; emergency

response; communication; and regional coordination.

SUGGESTED NEXT STEPS

Industry actively participates both in self-assessment and continuous improvement in all aspects of its sealed source and radioisotope production and distribution business. Industry also integrates closely at all levels in the regulatory development and implementation process. From these various perspectives, industry suggests that the following be considered in order to optimize future effectiveness and efficiency of sealed source transport and use:

1. Harmonization of security requirements and regulations on a global basis
2. Where conflicts or inconsistencies exist now, move towards an agreed upon set of requirements amongst Member States
3. IAEA prepares a master list of all security requirements existing on a global basis associated with RAM transport
4. As per ISC, establish (with existing or new) National Focal Point (NFP) type contact in each MS and Regional Coordinators (RC) to whom issues with security are addressed and managed
5. Recognition of the significant experience and the integration of safety & security requirements in RAM transport. Changes in regulations or procedures / processes should only be made where such changes are required based on risk determination (i.e. no change simply for sake of change)
6. Recognition of source and container integrity and positive safety and security experience over decades of use
7. Recognition of practical limitations of individual source tracking (i.e. RFID) and package tracking
8. Integrate with the industry to provide assessment of practicality of proposed regulatory requirement from a shippers' and a shipping perspective
9. Integration of other organizations (i.e. Customs) where their involvement ties into proposed security changes
10. Provision for flexibility in securely handling disused/spent sources
11. Recognition of radioactive material end use and activity shipped when considering any changes to existing security measures

These recommendations follow in part from the positive safety and security experience this industry has developed and integrated over the years and, where possible, ties in with other initiatives (often transport safety related) that the IAEA has introduced in the past.

CONCLUSION

The ability to effectively and efficiently ship radioactive sealed sources, medical isotopes and other radioactive materials is imperative for the industry producing them, and equally important for the industry and public who rely on them for health, safety, security, and commercial reasons.

The global radioactive material industry has a long history and an equally long and impressive safety and security record. It has worked hard to earn this enviable position. In conjunction with the broad and comprehensive regulatory environment – international, national (Member State) and local, the partnership between industry and regulators at all levels is strong and potentially, unparalleled globally. The integration of industry with government and regulators helps to ensure that new or modified regulations or requirements consider and often incorporate industry best practices, and while ensuring safety and security during transport and use, generally work well to help maintain effectiveness and efficiency. Regulatory compliance as the minimum standard is the cornerstone of ISSPA member companies' regulatory philosophy. Additional efforts, a Code of Good Practice and an ability to effectively work at all levels of the regulatory setting process, help to ensure industry's

reputation is maintained.
There are some issues that have an adverse impact on the ability to move product but the joint efforts and the willingness to work together to find workable solutions, is not only impressive, but imperative. Some recommendations have been provided in this paper which ISSPA feels will help foster the joint ability of industry, government and international bodies to ensure ongoing safety and security in the global transportation and use of radioactive sealed sources.