

**Addressing Concerns about the Denial of International Shipment
of Radioactive Sources-10357**

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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.

Use of radioactive sources in these sectors requires their safe and secure transport both within and between countries to ensure that developing and developed countries have access to this technology in a timely and cost effective manner. However, delay or denial of shipment of radioactive sources has a negative impact on the timely availability of this safe and beneficial technology. What are some of the key issues causing denial of shipment? How serious is this issue? What are international agencies, regulators and industry doing about it? In 2009, ISSPA was the Chair of the International Steering Committee on the Denial of Shipment of Radioactive Material. What are some of the key activities that the International Steering Committee is engaged in? What accomplishments have been achieved and what are the areas that still require international effort amongst key stakeholders? ISSPA will provide industry perspectives on how the issues causing denial of shipment can be addressed.

This paper will discuss the above and will provide some examples to show how ISSPA has been actively involved in addressing this issue.

INTRODUCTION

Radioactive sealed sources benefit a widely varied set of applications around the world. Many of these applications require the prompt and effective transport of these products 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 the radioactive sources. These applications are described below and the issues which adversely affect the industry through transportation delays and denials are discussed throughout the remainder of this paper.

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 offices and 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 some 45% of all single use medical disposables such as sutures, catheters, syringes, heart valves, artificial joints and about 80% of all surgeons' gloves. In fact, certain 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 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. 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.

The International Source Suppliers and Producers Association is an industry association comprised of 16 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. One of the initiatives that ISSPA is actively engaged in is the denial of shipment of radioactive sources.

DENIAL OF SHIPMENT

What is a denial?

Shipments of sealed sources occur daily by all modes of transport through a wide variety and size of carriers, and throughout ocean, air and border Ports globally. The vast majority of these movements occur routinely and without issue. The transportation of radioactive materials is highly regulated at the international level through such United Nations organizations as the IAEA (International Atomic Energy Agency), IMO (International Maritime Organization), and ICAO (International Civil Aviation Organization). In addition, 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 also govern the movement of these products around the world. Finally, Ports through which these products pass will also institute controls to which these products, in transport, must abide. The level of control established for shipment of radioactive sealed sources is, therefore, significant and detailed.

Since September 11, 2001, these regulations, focused primarily on safety, have been supplemented with globally instituted security enhancements. These include transportation security plans and programs required of the shipper and the carrier; personnel security checks; and in the US, specific requirements via safeguarded information; and significant administrative controls applied to Category 1 and Highway Route Controlled Quantity carriage.

ISSPA has established a Code of Conduct for its member companies. This Code calls on all industry members to use national and international regulations as a baseline, and to institute them into their business as a minimal standard. Further, given that the industry is shipping radioactive materials throughout the world on both cargo and passenger conveyances, controls on the types of containers used to carry the product are highly specific and also tightly regulated. The two types of containers used in such carriage are Type A and Type B containers, with the former being used for small activity source shipments and the latter for larger activity shipments. Necessary and regulatory controls exist for the testing and licensing of these containers, prior to their availability for use.

Shipments by air are generally restricted to sources with lower levels of radioactivity while the sources with larger activity are shipped by road, rail and sea. While all sources are shipped in accordance with transportation security and safety regulations, the larger the source or the greater the activity, the broader and more stringent the regulatory requirements which apply.

Given the very controlled environment in which the processing, preparation and shipment of sealed sources occurs, it is not surprising that the IAEA has stated (IAEA International Conference on the Safety of Transport of 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.” When conducted in compliance within the existing regulatory framework, the transport of these products, undeniably critical to society and important to the global economy is extremely safe. However there are instances when all regulatory controls and requirements are met, the regulator, the Port, the Carrier, the Handlers, etc. refuse to carry the product or allow the product into or through their jurisdiction. These denials of shipment are significant; affecting suppliers, consumers, industry, government, construction, patients, carriers and all others impacted by the inability to effectively move or receive these products. Further, it is not just the supply of these products that is adversely impacted by denials, it is also the ability to transport the spent or expired sources back to the manufacturer or to the waste disposal site that is adversely affected.

Why are denials occurring?

Denials are occurring globally however they do tend to be concentrated in different geographies, based on origin of supply, supply chain accessibility and capability, available routings to customer sites, and type of sources being moved. Products being shipped can be small check sources or sources used in smoke detectors, to higher activity sources transported in heavily shielded containers. The ability to predict where and when denials will occur is difficult given that changes which lead to denials are random and vary from one geographical area to another and from one time to another. The current global economic situation has further exacerbated this inability to predict.

For example, in shipping sources by sea, carriers' routes change depending on the markets they serve. Approvals are required through each ocean Port through which the ship passes, and as routes change, so do the Ports. Some Ports restrict or forbid radioactive materials from passing through or being retained at that Port while awaiting a connecting ship. In addition, to maximize the utilization and efficiency of ships, carriers will "co-share" with another carrier in order to carry a full load, vs. two ships carrying less than full loads. In such cases, the more restrictive requirements of the two shipping lines will apply, meaning that even if the ship actually carrying the product is your regular carrier of sources, but the co-share partner restricts on their ships the carriage of radioactive materials, then there will be no carriage of the sources.

In shipping by air, routine denials of radioactive source carriage occurs when the airline or the pilot deny their loading if the aircraft is carrying live animals, biological samples or even human remains. There are no regulations existing which preclude such carriage, yet a perception exists which adversely affect the ability to move sources effectively by air.

As can be seen, denial of shipments are widespread, cover all modes of transport, are unpredictable, and all have the same negative impact on the industry to effectively ship sealed sources to the point of use.

What is causing denials?

The IAEA has conducted significant research into the cause of denials and have identified five reasons:

1. Negative perception about radiation due to a lack of awareness and information about the industry.
2. Concerns about the cost and extent of training required of those who handle radioactive materials.
3. Multiplicity and diversity of regulations governing the handling, use and transport of these products.
4. Lack of harmonization between governments of these regulations which should be international and consistently applied. The end result of reason 3 and 4 is that there is duplicative, overlapping and sometimes contradictory regulatory requirements.
5. Lack of outreach and lack of public awareness about the needs and applications of radioactive materials.

What is being done to address the issue of Denial of Shipment?

ISSPA is working together with other industry associations, IAEA, IMO and ICAO to raise awareness and resolve the issues which are causing delays and denials of transport of radioactive sealed sources, medical radioisotopes, and other radioisotopes used in the electronics industry. Participation with supply chains, with regulators, with authorities involved in the transport process, and with the media to help educate the public and those involved are key to moving this issue to be one of facilitated, versus denied transport.

IAEA/IMO/ICAO

The IAEA/IMO/ICAO are working together and form the UN organizational leg of the International Steering Committee on the Denial of Shipment of Radioactive Materials (ISC). The ISC was formed and met for the first time in 2006, at the IAEA headquarters in Vienna. Also participating at this original meeting were a number of Member States, industry associations, NGOs (Non-Government Organizations), and some specific industries. Meetings have been held annually in Vienna with conference calls occurring throughout the time in between formal meetings involving the ISC management team and on occasion, the remainder of the ISC. The management team of the ISC is comprised of three elected individuals, a Chairman and two Deputy Chairmen. The Chairman rotates out each year (to remain as an emeritus Chairman), and the more senior of the Deputy Chairmen move into the Chairman's role. The other Deputy moves into the senior deputy Chairman role and a new Deputy is elected. In this way, there is a three year term for the management of the ISC, allowing ongoing experience and knowledge to be retained. Further, it was agreed that there would be at least one member of the management team being an industry representative; the rationale being that it is industry who would have the finger on the pulse of the severity and magnitude of the denial situation. ISSPA has served on the ISC management team since its inception was the Chairman in 2009. In addition to these three participants, the ISC management team incorporates IAEA staff that has responsibility of the denials "file".

The IAEA ISC is comprised of some 40 members, with greater than 20 countries represented, plus, as noted, NGOs and IAEA/IMO/ICAO, as well as industry associations and some specific industries.

The mandate of the ISC is to **develop a comprehensive Action Plan which will facilitate the global transportation of radioactive materials.** The Action Plan has been developed to address the reasons for denial and is updated at each ISC meeting. Significant emphasis is placed on providing each member with specific actions. In this way, the ISC is able to achieve significant and ongoing progress towards resolving those issues which cause shipping difficulties. National focal points and regional networks have been established to address issues and implant the Action Plan locally and regionally.

The ISC Action Plan is comprised of six foci: Awareness, Training, Communication, Lobbying, Economics and Harmonization.

Denial database:

To monitor the frequency of denials, as well as location, mode, and specific causes for them, the IMO with the IAEA developed a Denial Report Form and a Denial Reporting Process. An important part of the process requires the shipper or processor who is experiencing a denial to work with the organization which denied the shipment to try and resolve the issue. In this way, the first steps towards resolution are one on one between the two parties closest to the issue. It is expected that any Denial Report Forms submitted will be genuine, representing a significant barrier to effective and efficient trade and transport.

Denial reports are provided to the IAEA, IMO or ICAO where they are entered into the Denial Database which is shared amongst these UN organizations. To the end of September 2009, the database comprised of some 150 denial reports entered, with an additional 60 – 70 waiting to be entered. In addition, an industry association representing medical radioactive material processors and shippers has approximately 200 additional denial report forms that are about to be submitted. The Reports are analyzed by the IAEA/IMO/ICAO from the perspective of determining trends (i.e. consistent location, consistent carrier, consistent Port, etc.) and determining what the root cause is of the denials. These trends are then incorporated into the ISC Action Plan, with the aim of working with the organization(s) involved to discuss the issue and hopefully resolve the reason for the denial.

As a result of the data and the facilitation process, some significant improvements have been achieved in dealing with denials in a few regions of the world where there have been ongoing issues. For example, an issue existed through a Port in Latin America, where restrictions by the Port Authority resulted in shipments of radioactive sealed sources being denied, thereby precluding source shipments into and out of several countries in that region. Through the Latin American Regional Network, industry association, and specific industry involvement, issues of concern in the Port were raised and discussed with the parties noted. The practical exchange of information, the resultant education and awareness which arose, and the ability to provide fact resulted in the issues being resolved at the Port and the movement of sealed sources to occur in and out of the affected countries.

In another case, industry and the IAEA met with diplomatic levels of a country in the Asia Pacific which, when combined with discussions of the issues with that country's regulators, resulted in the issues being better understood, administrative actions being implemented and solutions established. This, collectively, resulted in the country, the Ports, and the regulators coming to agreement and ultimately allowing "in-transit" shipments through that country to a number of other countries in the Asia Pacific which could not, previously, move the radioactive sealed sources into those countries.

Finally, we are seeing a number of airlines moving in the direction required to allow carriage of small sealed sources that previously had been disallowed. This occurred because of initiatives undertaken by industry, industry associations, and the International Air Transport Association (IATA) through education, awareness and the development of a video specific to the air transport of radioactive material. These examples all show the importance of the practical and realistic actions incorporated in the ISC Action Plan.

ISC ACTIONS UNDERWAY

A brief review of some of the initiatives to support the ISC Action plan are listed below. Note also that each of the Regional Networks has these specific actions in place so that they can impart their regional and collective wisdom into their resolution.

Awareness:

- denials database development, trend evaluation, and communication to industry globally via NFP and Member States (to ensure magnitude of denials and examples are fully understood)
- developing a website for providing information required for submitting denial reports
- establishing a database of national and local competent authorities

Training:

- develop an e-learning package for Class 7 Dangerous Goods
- develop 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
- identify conferences and opportunities to communicate denial issues with organizations and conferences globally

Communication:

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

Lobbying:

- attend and articulate in other UN organizations' meetings to "de-mystify" the use and transport of radioactive materials and to discuss issue and impact of denials
- identify stakeholders who are key to the sustainability of radioactive material transport
- develop an outreach program which will positively influence and educate stakeholders
- hold regional meetings involving all stakeholders

Economic:

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

Harmonization:

- identify all regulations globally that impact transport of radioactive materials, analyze for inconsistencies
- NFP and RN initiatives
- examine interface and overlap between regulations dealing with radioactive materials at international and regional levels
- propose methodology for reduction of overlaps between regulations

CONCLUSION

The inability to effectively and efficiently ship radioactive sealed sources is imperative for the industry producing these sources, and equally important for the industry and public who will use these sources for a multitude of practical and beneficial purposes. The reasons for denials are varied but a statistical review of existing denial reports show that the reasons can be categorized into a relatively small number. These have been defined and form the skeleton of the IAEA's ISC Action Plan, in which the ISC members, the National Focal Points and the Regional Networks work on a global basis. These actions result in subsequent actions such that the Action Plan has become a living document. The results of these actions are having a positive and beneficial effect with some successes already being seen. ISSPA

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will continue to collaborate with other industry associations, national regulatory authorities, and all Non-governmental organizations involved in the movement of sealed sources to raise awareness of the significance and importance of rectifying the issue of Denial of Shipment of Radioactive Materials.