DENIAL OF SHIPMENT OF RADIOACTIVE MATERIAL

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Abstract
Radioactive sources are used globally in a wide range of beneficial applications in the health care industry, in industrial exploration and development, as well as in 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 world. Other vital applications such as cancer treatment, nuclear medicine, oil exploration and industrial radiography routinely and extensively use radioactive sources. In addition, radionuclides and radiopharmaceuticals are used tens of millions of times every year in the diagnosis and treatment of disease in patients globally. The ability to use such radioactive materials in these sectors is dependent on their safe and secure transport both within and between countries, and to ensure that both developing and developed countries have access to this technology in a timely and cost effective manner. However, delay and / or denial of shipment of radioactive materials is having a negative impact on the timely availability of this safe and beneficial technology. What are some of the key reasons for denial of shipment? How serious is this issue and what is its impact on industry and the public? What are international agencies, non-government organizations, regulators and industry doing about it? In 2009, ISSPA (**International Source Suppliers and Producers Association**) Chaired the International Steering Committee on the Denial of Shipment of Radioactive Material, and has again assumed this role in 2010 due to the incumbent Chairman's professional role taking him away from this key function. What are some of the key actions that the International Steering Committee has undertaken? What accomplishments have been achieved and what areas still require international effort amongst key stakeholders? This paper will provide industry perspectives on how the issues causing denial of shipment can be addressed, and how dealing with the root causes of denials will have marked positive impact on the industry and public who rely on them each and every day. Further, this paper will provide some examples to show how ISSPA and other industry associations such as iiA (**Industrial Irradiation Association**), CORAR (**Council on Radionuclides and Radiopharmaceuticals**), and AIPES (**Association of Imaging Producers and Equipment Suppliers**) have and can be actively involved in addressing this issue.

Introduction
Radioactive materials are key to a wide variety of applications around the world. Many of these require the reliable, fast 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 and relies on those radioactive materials. Since radioactive materials are always decaying, the need for prompt and effective, reliable transport is most important with those products which have short half-lives, specifically those products used in nuclear medicine procedures. Typically, these

products have half-lives that are measured in hours, hence any delay will adversely impact the ability to obtain a good diagnosis or an effective treatment of existing disease. These widely varied 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 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: 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, 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 diagnosis and treatment of a multitude of diseases. Further, Cobalt-60 is used to sterilize approximately 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, 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 critically 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 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. CORAR www.**corar**.org and AIPES www.**aipes**-eeig.org/index.php?id=2 are industry associations comprised of companies in North America and the EU respectively, which represent the producers and suppliers of nuclear medicine products used in the diagnosis and treatment of disease, palliation and imaging processes. These industry associations are all actively engaged in is the denial of shipment of radioactive sources.

Denial of Shipment

What is a denial?

Shipments of sealed sources, radionuclides and radiopharmaceuticals occur daily by all modes of transport through a wide variety and size of carriers, and throughout ocean, road, air and border Ports globally. The vast majority of 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 organizations - the IAEA (International Atomic Energy Agency), IMO

(International Maritime Organization), and ICAO (International Civil Aviation Organization). 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 materials must adhere for shipment of radioactive materials is therefore highly specific and highly controlled.

Since September 11, 2001, these regulations, which primarily focused 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 or proposed to be applied to the vast majority of radioactive material shipments – both sources and nuclear medicine products.

Sealed sources shipped by air are typically restricted to products having lower activity while sources with high 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, the more specific and the more stringent the regulatory requirements which apply.

Industry Associations typically establish a Code of Conduct for its member companies. This Code calls on all 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, or in the courier network, controls on the containers used to carry this product 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, prior to their availability for use.

Given the highly and tightly controlled environment in which the processing, preparation and shipment of these radioactive products occurs, it is easy to see how the IAEA 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." 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. However, 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 the product or allow the product into or through their jurisdiction. In fact, the IAEA defines denial of shipment as ""***an (explicit or implicit) refusal to carry a radioactive shipment though it conforms to all the applicable international regulations***". In other words, from a regulatory safety and security perspective, non-compliance of 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, carriers and all others impacted by the inability to effectively ship or receive 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.

Why are denials occurring?

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. Products affected vary from small check sources or sources used in smoke detectors, to higher activity sources such as those used in medical disposable product sterilization and transported in heavily shielded containers. In addition, nuclear medicine radioisotopes and radiopharmaceutical products (often in mCi activity quantities) are adversely affected. 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 the increased security environment in which we live and work has further exacerbated this inability to predict.

For example, in shipping sources by sea, carriers' routes change depending on the markets they serve or the time of year the shipment is occurring. Approvals are always required from 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 waiting to connect with another ship. In addition, to maximize the utilization and efficiency of ships, carriers may "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, but the co-share partner has restrictions on 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. Further, some international airports have only a few carriers' handlers moving product for all carriers within that airport. If that carrier does not carry radioactive materials, then their staff is not trained to do so, and this essentially precludes use of that airport by all carriers who are capable and willing to transport these products into that location.

In summary, denial of shipments is widespread, covers all modes of transport, is unpredictable, and has the significant negative impact on industry regarding effective transportation, and on the public regarding reliable availability.

What is causing denials?

The IAEA, with IMO, and ICAO 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?
Industry, through such associations as ISSPA, iiA, CORAR, and AIPES, is working 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, rather than denied transport.

IAEA/IMO/ICAO
The IAEA/IMO/ICAO collectively 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. General Conference Resolution GC(49)/RES/9 (2005), encouraged the Agency to constitute an International Steering Committee to oversee the resolution of the issue of denials of shipments of radioactive material.
General Conference resolution GC(51)/RES/11 of September 2007, urges the Secretariat to actively facilitate the work of the Steering Committee on denials of shipment of radioactive material and identifies key tasks.
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 with conference calls occurring between formal meetings and 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 a member of the ISC Executive Committee), with the more senior of the Deputy Chairmen moving 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 representing industry, the rational being that it is industry who will 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, and has chaired the ISC in 2009 and 2010. 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.
Two key actions instituted by the ISC through the IAEA have been the establishment of the National Focal Point (NFP) and Regional Coordinator roles. The NFP is the individual in their country who acts as the central and common point of contact for all IAEA matters related to denials and delays of shipment of radioactive material. As at May 2010, 69 Member States (countries) have identified and duly nominated individuals to act as NFPs.
The roles and responsibilities of an NFP are:

- To serve as the principal focal point for intimating and advising appropriate agencies (both governmental/non-governmental) on all aspects of denials and delays of shipment of radioactive material (RAM);
- To serve as the interface between his/her government, the Regional Coordinators and the Denials Secretariat in all matters related to planning, facilitating and monitoring of shipments of radioactive material and evaluating the reasons for denials;
- To serve as a resource centre for knowledge about the IAEA's denials of shipment programme and ensure that lessons learned and proposed corrective actions, adaptations and innovations for future solutions are documented and reported to the Regional Coordinators and Denials Secretariat;
- To interact with network members, NFP counterparts, Regional Coordinators and the Denials Secretariat with a view to resolving issues relating to the denial/delay of shipments of radioactive material.

In addition, the IAEA has established, to date, five Regional Networks which constitute a number of countries in a specific geographic part of the world. The Regional Networks currently in place include: Latin America, Asia Pacific, Mediterranean. English speaking Africa, and French speaking Africa. One NFP from each of the Regional Networks serves as the Regional Coordinator and has as a primary role, the facilitation of communications and actions between that Regional Network and the IAEA.

Throughout 2007, 2008 and 2009 many regional workshops were conducted. A common recommendation to the Steering Committee was that a technical meeting should be held for the NFPs. It was decided by the Steering Committee to have the first technical meeting for NFPs on Delay and Denials of Shipment of Radioactive materials held in the same week as the Regional Coordinators meeting and the Fifth International Steering Committee on Delay and Denials of Shipment of Radioactive Material (2010). This action was so successful that it is being carried out again at the next ISC meeting in early 2011.

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

Awareness	- Institute a database to record all denials (all modes, all geographies) - Access data, define root cause of denials, establish action plan to resolve - Educate all parties involved of the very rigorous standards in place re transportation
Training	- Improve awareness and understanding of transportation supply chain and stakeholders regarding transport safety regulations and experience
Communication	- Improve the integration and transparency between producers, shippers, users, carriers, Authorities, regulators and the Public
Lobbying	- for marketing, outreach, and promotion of industries shipping radioactive materials and for promoting a positive image regarding the use of these materials
Economics	- Mitigate deleterious & burdensome costs associated with shipping denials & delays
Harmonization	- international & national regulations and standards, of Port & Port Authority requirements, of carrier requirements & of denial report process

Denial database:

To monitor the frequency of denials, as well as their location, mode, and specific causes, 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 ransport. 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. As of mid-2010, more than 200 denial reports had been entered into the database, with a further 200 making their way through the system from originator to IAEA. 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 the root cause 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. From a geographic and regulatory perspective, the National Focal Point and perhaps the Regional Network will get involved to help facilitate discussion and resolution.

The data and the ISC action process has had some positive effect and continues to both maintain awareness and facilitate resolution of denial 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 and medical radioisotopes 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 are just a few of the success stories and all show the importance of the actions and processes underway via the ISC.

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, 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 safety, security, health and commercial reasons. 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. Industry associations such as ISSPA, CORAR and AIPES will continue to collaborate with other industry associations, national regulatory authorities, and all Non-governmental organizations involved in the movement of sealed sources and radioisotopes to raise awareness of the significance and importance of rectifying the issue of Denial of Shipment of Radioactive Materials.