Denial of Shipments – Myth or Reality

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Abstract

The global healthcare community depends on shipments of radioisotopes. MDS Nordion manufactures and distributes radioisotopes used in the medical, research and sterilization industries throughout the world. With a growing demand for radiation and radiation technology to prevent, diagnose and treat disease, it is important that the global health care industry have a secure and reliable supply of such important materials. Despite this ever increasing need, shipments of radioisotopes are being increasingly delayed and outright denied.

This paper outlines the importance of radioisotopes to global healthcare. It also details examples of shipment denials and how this evolving situation has impeded the efficient transport of radioactive material which risks preventing the delivery of essential radioisotopes to many member states.

Denial of shipments was identified as a key issue at the 2003 International Conference on the Safety of Transport of Radioactive Material, the 2003 International Atomic Energy Agency (IAEA) General Conference and at an IAEA Technical Meeting in January 2004. The outcome is that the IAEA is focused on better documenting the problem and is starting to develop ideas to address it. Moreover, governments, associations and modal organizations are becoming more aware of the matter.

As a responsible partner in a unique industry, MDS Nordion encourages all IAEA Member States, commercial carriers, airports and ports to be engaged in this matter and accept the transport of radioactive material without additional requirements. In this respect, the collaboration of all organizations involved in this highly interactive global system of transport is vital to assure the effective transport of radioactive material for global health care.

Introduction

Most countries are importers of radioisotopes. The effective movement of these materials is therefore essential for the patients, physicians, and consumers that depend on them every day around the world. This paper will explore the problems encountered with the denials of shipments of these materials and their impact on the movement of radioisotopes used in global health care. The small number of isotope producers in the world – and their global customers – are concerned with the increased complexity of transporting this material and the increasing incidence of shipment denials. This situation is made more significant in that there is a growing demand for radiation and radiation technology to prevent, diagnose and treat disease. In short, the global health care industry is depending on a reliable supply of radioisotopes.

The IAEA transport regulations were drafted in 1959 to reduce both risks and costs as well as to facilitate the expanding international trade of radioactive material. The highly interactive global system of regulatory control that has evolved over the years has achieved a very high standard of safety in transport. Nonetheless, the number of commercial carriers, airports, ports and handling facilities not accepting radioactive material has been increasing. The denial of shipment issue has recently received international attention at the 2003 International Conference on the Safety of Transport of Radioactive Material and at subsequent IAEA meetings in 2004, as well as by modal organizations.

One outcome of these meetings is a growing acknowledgement that there is an issue. There is also a need to more fully document the denial of shipment problem. As well, these meetings have pointed to some of the factors affecting shipment denials including carrier/government policy, additional requirements and restrictions, pilot refusal, variations in the implementation of the IAEA regulations, commercial considerations and security concerns. Case studies will be presented to demonstrate actual denial of shipments and how they have impeded the efficient transport of radioisotopes.

Ensure Global Health Care

The air and marine carriers are an integral part of ensuring a secure, timely and reliable supply of radioisotopes used for global health care. Clearly the transport modes are essential links in the distribution chain. Radioisotopes producers, such as MDS Nordion, depend on these linkages to distribute this material worldwide. MDS Nordion supplies well over sixty percent of the world's medical isotopes.

Diagnosing Disease

"Every 3 seconds [notes the IAEA] a person receives some kind of radioisotope treatment for medical diagnosis...".[1] Hospitals and nuclear medicine physicians require a reliable and timely supply of medical isotopes. Given that these materials are highly perishable due to their short half-lives, they require immediate shipment. Air transport is critical. Medical isotopes are relied upon for administration to patients within hours of delivery as well as being available for use in emergency medicine.

Nuclear medicine procedures provide physiological information about how a patient's body and organs are functioning. It provides disease detection before anatomical changes are apparent. Physicians are able to see, for example, whether the heart has been damaged following a heart attack. Molybdenum-99 – one of the world's most important medical isotopes – is used in over 75% of all nuclear medicine diagnostic procedures, such as for brain disorders, heart conditions and in cancer diagnosis. Thousands of diagnostic procedures occur everyday around the world based on the supply of this one isotope, alone. This short-lived isotope is used exclusively as a pharmaceutical. Shipments are made to radiopharmaceutical companies, which in turn, supply thousands of hospitals and clinics. A variety of medical isotopes are used in some one hundred diagnostic applications and they are also used to treat brain, prostate cancer and non-Hodgkin's lymphoma, a devastating blood-borne cancer. Dependable air transport largely ensures that global nuclear medicine can continue to diagnose and treat disease.

Treating Disease

Radiation is an integral part of cancer therapy. Approximately 50% of all cancer patients are treated with radiation. MDS Nordion's external beam teletherapy machines, alone, deliver 45,000 cancer treatments daily in over 50 countries. Teletherapy sources are transported by all modes.

According to the World Health Organization, there are currently 10 million new cases of cancer diagnosed globally each year and it is expected that in the next twenty years that figure will increase to 15 million. The World Health Organization has also estimated that by 2020 nearly two-thirds of the worldwide cancer cases will occur in the developing world [2]. The IAEA declares that there is a "silent crisis" in treating cancer in the developing world. The developing world represents 85% of the world's population but only about 33% of the total radiotherapy facilities. Cancer takes more lives than HIV/Aids, TB and malaria combined. In short, the developing world requires adequate cancer treatments and radiation technology, such as that provided by cobalt-60.

Preventing Disease

It has been estimated that some 80% of all surgeon's gloves have been sterilized using gamma irradiation technology. The healthcare community and society at large depend on the sterilizing applications of cobalt-60 to prevent the spread of infection and disease. Global transportation is also essential for this radioisotope. Cobalt-60 is used to sterilize over 40% of the world's disposable medical supplies and a vast array of consumer products.

Just-in-time manufacturers of medical supplies depend upon a reliable supply of high activity cobalt-60 to be used to sterilize their products such as surgeon's gloves, syringes and sutures which are used in operating suites, hospitals and clinics worldwide. The gamma irradiation technology plays an important role in preventing disease as it virtually eliminates pathogens and bacteria that may cause infection or disease. Many products found on the shelves of pharmacies have been sterilized using this technology, such as contact lens solution and bandages.

MDS Nordion has shipped over 70,000 sealed sources and over 500 million curies (20,000 PBq) of cobalt-60 safely throughout the world for over 40 years. More than 120 MDS Nordion irradiators, the irradiation facilities that undertake the sterilizing process, have been installed around the world. Every year more than 30 million cubic meters of heath care supplies are sterilized with gamma irradiation. Similar to the radioisotopes used to diagnose

and treat disease, there are only a handful of suppliers of cobalt-60 and most countries are importers of this material, or the processed products that have been sterilized by it.

Preventing food-borne illness

Food-borne illness claims thousands of lives worldwide each year. The United Nations reports that contaminated food is "perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic activity." The U.S. Center for Disease Control estimates that every year in the United States, alone, 76 million people become ill due to microbial contamination, and 5,000 people die. [3]

Over 40 countries have approved food irradiation for over 50 different foods such as shrimp, beef, chicken, spices and potatoes. The potential uses of food irradiation are numerous. There is increasing interest in food irradiation due to high food losses caused by spoilage, infestation and contamination. The United Nation's Food and Agriculture Organization estimated that nearly 25% of all food production is lost to insects, bacteria and rodents after harvest. Food irradiation can play a key role in reducing this loss. Today, well over 80% of spices and seasonings used in dried noodles in Asia have been irradiated. Cobalt-60 can play an important role in helping to make the food supply safer.

Denial of Shipment

The use and demand for radiation technology and products are important for the prevention, diagnosis and treatment of disease. But the radioisotopes that are required to fulfill these health benefits are facing increasing challenges in getting to the end-user. The transport of radioisotopes is a vital part to the global medical isotope supply and, ironically, transport issues are creating serious impediments to doing so.

Fortunately, denial of shipments is becoming a recognized issue internationally. At the IAEA 2003 General Conference, the Agency supported a resolution to recognize the problem of denial of shipment. A follow up technical meeting in January 2004 developed an action plan and set the groundwork to collect more information on this issue. Through the collaboration of the UK competent authority, instances of denial of shipment were collected from the industry worldwide and presented to the Transport Safety Standards Committee (TRANSCC) in March 2004. TRANSCC recognized the issue and requested the IAEA to collect more information. The IAEA hosted a fact-finding mission in July followed by a Consultants Meeting. Its report developed a more detailed implementation plan to address denial of shipments, which will be considered at the September 2004 General Conference. Importantly, this report acknowledges that action can be taken on denials on a variety of fronts. There remains a need to document denial problems better, smooth out regulatory impediments, address the lack of harmonized rules and practices, reduce administrative burdens, tailor better training programs to handle radioactive materials, improve communication and education to help address these complex issues, and facilitate denial problems among those affected. All these, and more, need to be pursued.

An important part of addressing the issue is raising awareness of the problem. The International Maritime Organization (IMO) considered denial of shipments of radioactive materials, notably cobalt-60 at a recent meeting. It concluded that shipments of cobalt-60 have a "humanitarian dimension" which is "in the interest of public health and this is for the benefit of the society at large"[4]. Additional consideration of this issue is also to be done by the IMO in September 2004. In addition, the International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA) have been involved in the IAEA process and have been contributing to finding ways to address denials occurring in the air mode. For the first time, IATA invited shipping companies to discus the roadblocks to the air transport of dangerous goods at it's Dangerous Goods by Air Conference in March 2004.

Recognizing that no one entity can "solve" the issue, a collaborative approach is required among all parties, including IAEA member states, carriers, modal organizations, associations, seaports and airports, and radioisotope producers, to facilitate the acceptance of radioisotopes. MDS Nordion recognizes that it is essential to better understand why denials are occurring among carriers, ports and authorities. We need to address the questions and concerns people have on this complex matter. Two-way communication is fundamental.

As it relates to security, radioisotopes are manufactured and transported according to stringent standards and in compliance with new security requirements. As a leading global medical isotope supplier, MDS Nordion wants to pursue global solutions by working closely with suppliers, customers and regulators to ensure that its radioisotope handling processes remain among the safest and most secure in the industry. Practical and effective requirements

for safety and security are required to ensure the continued availability of these medical isotopes for global health care.

Harmonized Implementation of Requirements

The Dangerous Goods regulations and the IAEA regulations were developed to reduce both risks and costs as well as facilitate the expanding international trade of these goods. The highly interactive global system of regulatory control that has evolved over the years has achieved a very high standard of safety for the transport of radioactive material. Uniform implementation of these requirements with minimal variations is essential to continue to ensure a high degree of safety as well as the effective transport of radioisotopes for global health care. Uniform implementation and fewer variations will simplify international transport and reduce the regulatory burden imposed on all carriers and Member states and hence facilitate the effective transport.

Case Studies

Some airlines and shipping lines have stopped transporting radioactive material altogether while others have highly restrictive policies. Similarly ports and countries have either refuse in-transit shipment or have very restrictive policies. There is a risk of other carrier, ports and countries doing the same. Consequently, this increases dependence on fewer airlines, shipping lines and critical transit hubs which increases the risk of a major shortage if a carrier or port declines to accept radioisotope shipments.

Airline Refusal

1. Examples of airlines not accepting Class 7 goods:

   KLM, British Airways, Northwest Air, Fed-Ex Europe, Thai Air & Turkish Airlines

2. Examples of restrictive policies:

   Delta Airlines' internal policy dictates that Type A packages with a Transport Index (TI) of more than 3 are not accepted even thought the transport regulations limit the TI to 6.

   For shipments to Japan, one airline will not accept Type B(U) packages on passenger aircraft. Hence, cargo aircraft must be used. As this airline has no cargo aircraft leaving Canada for Japan, all shipments of radioactive material must transit through the United States.

3. Examples of additional cost to meet regulatory requirements:

   Another airline will not ship to Japan from Canada due to the additional cost of meeting regulatory requirements to handle Class 7 goods.

   One Middle East airline has stopped transporting radioisotopes used in nuclear medicine due to the specific fees that had to be paid to the Competent Authority and the handling requirements and restrictions imposed for Class 7 goods.

Pilot Refusal/Bumping

4. Example of bumping:

   There are documented cases where airlines removed medical isotopes from flights because animals were loaded on the aircraft. In many cases the medical delivery was postponed to the next day for delivery to the hospital, which can delay patient procedures.

Shipping Companies Refusal

5. Example of shipping company not accepting Class 7 goods

   An Asian feeder vessel, which previously accepted Class 7 goods, no longer accepts Class 7 goods. Hence, the cobalt-60 shipment in question had to be re-routed which caused additional delays and expenses.

Port Refusal

6. Examples of ports not accepting Class 7 goods:

   Italian ports will not accept domestic and in transit shipments. Shipments for Italian customers must be routed through France for road/rail transport.

   Greek ports will not accept radioactive material for domestic or in transit shipments.

   A port in Mexico, recently refused an in-transit shipment. This required a change in carriers to one whose routing did not include Mexico; this delayed the shipment.

   The Oman Port authority refused an in-transit shipment.

   The Thai Port Authority will not accept transshipments of Class 7 goods. They will only allow Class 7 goods to enter the port for medical use in Thailand.

7. Example of restrictive policies:

   For shipments to the Middle East, the ship must arrive at the Port during official working hours. Consequently, one shipping line will not accept the booking since exact berthing time cannot be guaranteed in advance.

Port and Shipping Line Refusal

8. Example of the combined effect of these restrictions:

   Port denials and imposed shipping route restrictions (and the impact this is having on marine carriers) combined with the implementation of the Type C requirements on July 1, 2001, (large quantities of cobalt-60 can no longer be transported by air) have made it nearly impossible to transport cobalt-60 to, in one case, a specific East European country. Several possibilities were investigated, including shipping the package around the world to the Middle East and then transporting it by road. However, this required multiple ports of call, with the risk of having the shipment stopped at any one port along the way. A direct route through the Mediterranean Sea was not possible. After many attempts, the only route available was by sea to Northern Europe followed by road transport across Eastern Europe. This involved multiple endorsements from several Eastern European countries and lead to an eleven-month delay in transport. This translated in an approximate lost of 800 TBq (22 000 Ci) of cobalt-60 due to radioactive decay.

Nuclear Free Zone

9. Example of country policies:

   Acknowledging that medical isotopes and radiation technologies are beneficial shipments of cobalt-60 through one Caribbean country require a special approval because the Caribbean has declared itself a "nuclear" free zone.

Variations in the Implementation of the Transport Requirements

10. Example of the unilateral approval not being applied around the world.

    The IAEA regulations state that the package design be approved by the competent authority of the country of origin of the design only. (Hence, the Canadian Nuclear Safety Commission should be the competent authority approving the package design for Canadian designed packages.)

    To transport into or through the United States, the US Department of Transportation (USDOT) issues an endorsement of the Canadian certificate. The USDOT requires a complete copy of the Safety Analysis Report for their endorsement review, which results in having a second competent authority reviewing the same safety analysis report approved by the former competent authority.

    Similarly, for transport into or through Europe, the European Agreement concerning the international carriage of dangerous goods by road (ADR) requires that the first country of entry endorse a Canadian issued Type B(U)-96 certificate. In most cases, a portion or all the Safety Analysis Report must be submitted to that country for review. This may also involve the translation of the Safety Analysis Report into another language prior to submission. This results in a third review and approval of the same Safety Analysis Report.

Summary

The denials of shipment issue cannot be attributable to a single problem and can often be the result of a combination of factors. With the number of carriers accepting Class 7 goods declining, the risk of the "last remaining carrier" on a route denying shipment is increasing. Added to this is the growing number of key hubs in key countries denying shipments. This has negative implications for delivering radioisotopes to countries and is increasingly heading to an environment where there may be no delivery option.

Conclusion

Denial of shipments has resulted in delays, additional costs and outright prohibitions in delivering critical medical supplies to many member states. The IAEA Member States, carriers, modal organizations and others are showing leadership by becoming engaged on this matter. As a responsible partner in a very unique industry, MDS Nordion encourages all IAEA Member States, carriers, modal organization, airports and seaports to communicate with us and work with us to accept the transport of radioactive material without additional requirements. The world depends on an interdependent global transport system, which makes collaboration absolutely necessary among all organizations involved in this issue. Facilitating international shipments is vital to ensure the effective transport of radioactive material for global health care. People's health is depending on it.

References

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