Sustaining reliable shipments of IMO Class 7 Radioactive Materials

[1]Pete Lambourne, [2]Cathie Deeley

[1]Transport and Logistics Manager, [2]International Marketing Manager

REVISS Services (UK) Ltd.

6 Chiltern Court, Asheridge Road, CHESHAM, Buckinghamshire, UK HP5 2PX

Abstract

45% of the world's single use medical supplies are sterilised using gamma radiation from Co-60 sources. Both the Co-60 source manufacturer and the end-user are equally dependent upon the reliable transportation of class 7 radioactive material to approximately 200 sterilisation facilities in 80 countries around the world. Perceived risk associated with the handling of radioactive materials combined with disparity in local legislation is a growing barrier to acceptance of class 7 cargo for shipment. With increasing frequency a deadlock is reached between regulators and ports/carriers with the result that even fewer carriers are willing or able to carry this vital humanitarian commodity.

This paper sets-out to dispel the perceived risks and encourage the IAEA to improve accessibility to training, educational materials and harmonisation of regional legislation governing the passage of low volume Class7 radioactive materials for healthcare and humanitarian applications.

Introduction

The reliable transportation of radioactive materials affects all of us. For example, 45% of the world's single use medical supplies are sterilised using gamma radiation from Co-60 sources. If you have ever had an injection or used a sterile dressing you have already benefited from a global industry that has just two major manufacturers of cobalt-60 (Co-60) sealed radiation sources. Both the Co-60 source manufacturer and the end-user are equally dependent upon the reliable transportation of class 7 radioactive material to approximately 200 sterilisation facilities around the world.

Although medical devices are manufactured in clean-rooms and sealed in pouches they are not, at this stage, sterile. To manufacture high-consumption medical disposables, such as dressings, aseptically would be simply not cost effective. Fortunately whole pallet loads of medical devices can be sterilised

economically and efficiently in facilities processing anything between 20,000 and 200,000 m^3 of product per year, using gamma radiation from Co-60.

Medical device sterilisation utilizes approximately 60% of all radiation processing capacity; however it is not the only application of Co-60 radiation sources to benefit our everyday lives. Commercial scale radiation processing saves lives and benefits society in many other surprising ways:

Much food packaging is sterilised before use to minimise adulteration of food products with surface bacteria. Natural herbal ingredients used in cosmetics, pharmaceuticals and beauty products are sterilised to kill pathogenic organisms that might otherwise cause infection in the user; even contact lens fluid is made sterile using gamma radiation from Co-60. Feathers, originating from high risk communities for use in soft furnishings may be irradiated to prevent the transmission of bird flu to the human population. Mosquitoes are irradiated to render them sterile so that when they are seeded back into the environment, breeding fails and Malaria is gradually eradicated in the region.

Every day radiation is saving lives in our hospitals. For decades, food has been irradiated for patients with severe immune-compromised diseases to prevent food-borne illness. Bottle teats for premature baby units are sterilised using gamma radiation from Co-60. Blood for transfusion is irradiated to prevent occurrences of a fatal and unpredictable transfusion associated Graft versus Host Disease.

Irradiation of food has been researched for more than 100 years. In the USA alone, approximately 5,000 people die every year from food poisoning. Just 10 E-coli bacteria surviving in a barbequed hamburger can be fatal for a child! Some hamburger meat is irradiated in the USA to “pasteurise” it. Herbs and spices attract a high pathogenic bio-burden sometimes from contaminated irrigation water or raw fertilisers and frequently from animal droppings during the drying process. They can be sterilised using gamma radiation without impairing their flavour or colour.

All these applications illustrate the vital contribution that this single radioactive material makes to our everyday lives.

Environmental benefits

Radiation processing is also playing its part in environmental protection. Of particular benefit to Port and Harbour personnel is the use of irradiation in place of toxic fumigants. Methyl Bromide (MeBr) gas is used to fumigate produce before or during export, sometimes while in the ship’s hold, to kill quarantine pests and avoid infestation of the importing country. However, MeBr is a Class I cancer causing agent and is highly ozone-depleting. It was banned by the Montreal Protocol for agricultural use in developed economies by 2005 and in developing economies by 2015 but quarantine treatments are exempt from this ban. Irradiation, using Co-60 sources, is now being used at

the point of harvest to eliminate quarantine pests from mangoes exported to the USA from India, Pakistan and Thailand. Irradiation also slows the ripening process and inhibits sprouting, resulting in less food spoilage in transit. By replacing the use of Methyl Bromide, Co-60 is protecting Port Workers from contact with toxic gas, reducing food spoilage and helping to preserve the ozone layer from depletion.

Cobalt-60 is not a nuclear waste material it is manufactured from non-radioactive Co-59 metal in specialist reactors producing isotopes for healthcare applications as well as in some power reactors. Co-60 is a metal – it is not soluble in water and it is much more easily contained than dangerous chemicals transported as liquid, powder or gas. Co-60 has a short half-life of 5.27 years and decays to non-radioactive Nickel-60 at the rate of approximately 12% per year.

The Problem

The global radiation processing industry comprises just 200 facilities in 80 countries worldwide. They are supplied by two manufacturers of Co-60 radiation sources from four manufacturing sites; Canada, UK, Argentina and Russia. This supply chain comprises a total of just 100 - 200 ISO containers per year. Maintaining reliable shipping routes for a total consignment of only 200 class 7 ISO containers per year is a growing challenge for suppliers of radioactive materials.

Manufacturers have good relationships with carriers and port authorities in Northern European and the East Coast North American Ports, between which shipments are frequent; familiarity with the product has established routine procedures for its handling. However, since 9/11, the burden of paperwork and disparity in local legislation has grown in step with heightening regulatory control of class 7 cargo. As a result the miscellany of shipping routes necessary to supply this vital commodity to the rest of the world, at a much lower frequency, have become extremely difficult to sustain.

Perhaps the most significant barrier to securing reliable shipping routes from the UK to the Far East is the number of ports that must be transited *en route*. In the face of increasing legislation, many Mediterranean ports have become unwilling to manage the intermittent transit of class 7 cargos. Not surprisingly this has a big impact on the ability of carriers to accept such class 7 cargo. Further difficulties are encountered with routes that require trans-shipment; a number of hubs used by carriers are unable to accept Class 7 cargo for transhipment to feeder vessels. Even within ‘class 7-friendly’ ports, only specific terminals may be able to accept class 7 cargo; the carrier is unlikely to deviate from the preferred terminal to accommodate just one or two containers which further limits the number of shipping options available.

Disparity in local legislation is a growing barrier to acceptance of class 7 cargo for shipment. Demands placed upon the carrier by a port authority or local

regulators in one region are often considered to be unreasonable by shipping-line owners or regulators or port authorities in another region. With increasing frequency deadlock situations arise and even fewer carriers are willing or able to transport this vital humanitarian commodity.

These days it is not uncommon for the suppliers of radioactive materials to struggle for up to a year before a carrier can be found and a route secured to the less frequently accessed destinations.

The Facts

"In 40 years of shipping commercial quantities of Co-60, there have been no radiological incidents," said Eliana Amaral, Director of the Division of Radiation Transport and Waste Safety in the IAEA.

Co-60 sources are shipped in transport packages costing several hundreds of thousands of dollars each to manufacture; designed and built to the highest specification. There are stringent standards surrounding the packaging of radiation sources. The International Atomic Energy Agency (IAEA) is responsible for certification pertaining to these standards. Packages for the transportation of commercial quantities of radioactive materials must be approved under the IAEA Regulations for the Safe Transport of Radioactive Materials (TS-R-1, 2009). Type B(U) certification - required for packages carrying the larger quantities of material - requires the package to be tested, "to withstand transport accident scenarios under extreme environmental conditions" and be resilient to high-speed impact and fire. In the licensing process, an independent regulating authority (*in the UK it's the Department for Transport*), witnesses drop-testing of a prototype package onto a steel post in a hardened concrete target. The package MUST maintain physical product containment, radiation and thermal shielding throughout repeated drops from one to nine metres onto its most vulnerable components.

The routine intermittent handling of these packages by port workers will have no impact on their annual radiation dose uptake. A measure of the effectiveness of the radiation shielding used in Type B transport packages is that the measured annual dose absorbed by REVISS classified radiation industry workers, who handle these packages on a daily basis, is equal to approximately 2 units (milli-sieverts). This is less than the UK average 2.5 units (milli-sieverts)[i] of background radiation that we absorb each year from atmospheric emissions when we fly, through geological emissions from the natural environment or when we undergo medical x-rays etc.

The placement of ISO containers carrying such transportation packages in proximity to other ISO containers will have essentially no impact on the contents of adjacent ISO containers. The dose absorbed over a period of 1 month by packages located continuously at a distance of 1 metre from a typical REVISS transportation package is approximately equal to the dose absorbed during a medical CT-scan of the chest.

The Solution

Radioactive material, falls into class 7 under IMO's IMDG (International Maritime Dangerous Goods) Code. The carriage of material which falls into this class was discussed at the IMO's Facilitation Committee (FAL) in 2005. The committee agreed to continue its work to enable shipments of class 7 radioactive materials through resolving delays and denials of shipments. On occasion IAEA regional representatives have intervened and provided assistance securing shipments. However despite the active approach from IAEA and IMO the industry has not noticed a generic improvement in certain regions' attitudes towards handling such materials.

1. **Harmonise local, national and international legislation governing the movement of radioactive materials**

   In many cases the difficulty carriers find in gaining permission to transit cargo through ports *en route* to the final destination stems from conflicting regional regulatory requirements governing passage of radioactive materials. These often stem from misplaced political and environmental views that have legitimised local regulation which bans the passage of radioactive materials of any type, and consequently threatens the very quality of life it strives to protect.

   IAEA National Representatives should perhaps be tasked with

   i) Lobbying their Governments' Transport Ministry to acknowledge the need for reliable shipment of radioactive materials for healthcare and humanitarian applications and to repeal local legislation that hinders this

   ii) Producing educational material in local language for carriers, regulators and port workers on the humanitarian benefits of radioactive materials

2. **Improve availability of IMDG training on the handling of Class7 cargo**

   When class 7, radioactive cargo is shipped through a port on a regular basis, IMDG class 7 training for relevant personnel is kept up-to-date and routine procedures are developed. However, the class 7 element of the IMDG training schedule is extra to the basic course and many Shippers who encounter this class of cargo on an infrequent basis will not receive the training by default. A version of class 7 training could be included in the standard IMDG training course, focussing on the handling of Type B package shipments and providing templates and draft procedures to equip personnel for managing the transit or trans-shipment of radioactive materials in ports and harbours that encounter class 7 cargo at infrequent intervals.

3. **Debate the merits of defining a new UN category to help identify low volume class 7 RAM for healthcare and humanitarian applications**
   Only 100 – 200 ISO containers of Co-60 sources for radiation processing and medical application are shipped each year. Necessarily they are carried alongside non-radioactive packages. If this type of material could be flagged as having NO impact on the radiological welfare of personnel or materials in the vicinity perhaps the barriers to transit of radioactive materials could be lowered and requirement to trans-ship only at Class 7 terminals could be reviewed.

Conclusion and Call to Action

There are clearly strong humanitarian reasons for regulators/ authorities to review the management and implementation of shipping legislation for the transit of these materials. We would urge regulators/ authorities to press for the IAEA to strongly encourage the harmonisation of legislation controlling the passage of radioactive material and to simplify and recommend an element of class7 training to be included in the standard IMDG Dangerous Goods Training Schedule.

Until such times, sea freight carriage and routes will continue to be difficult to secure and worldwide healthcare will suffer as a result.

Reference.: i) Institute of Physics: Background Radiation - Measuring your annual dose http://www.iop.org/activity/education/News/Newsletter/file_31284.pdf