The Effects of Type C Packaging Regulations on the Shipment of High Activity Cobalt 60 Sources

Michael Krzaniak, P.Eng and Marc-Andre Charette P. Eng.

MDS Nordion Inc

447 March Road

Kanata, Ontario, CANADA K2K 2K9

Abstract

High activity Cobalt 60 sealed sources are used by the gamma processing industry for the sterilization of medical disposables. Typical shipments to industrial irradiators include PBq quantities of Cobalt 60. The implementation of the Type C requirements for air shipment has made shipments of typical quantities impractical. A case study is presented showing costs of compliance with these new requirements to be millions of dollars. Examples are also provided showing the importance of the air shipment. It is concluded that the benefits associated with this change in regulations have not been demonstrated and are outweighed by costs and other practical considerations.

Introduction

The gamma processing industry requires a reliable supply of high activity Cobalt 60 sealed sources. Large industrial irradiators often contain PBq quantities of Cobalt 60. Medical disposables are the main products sterlized using gamma radiation. These are used in operating suites, hospitals, clinics and other such applications.

MDS Nordion is a global leader in the supply of Cobalt 60 sources and industrial irradiators.

The introduction of the International Atomic Energy Agency (IAEA), Safety Standards Series Regulations No. TS-R-1 (ST-1 Revised), Regulations for the Safe Transport of Radioactive Material 1996 Edition (Revised) [1] in January 2001 introduced the new Type "C" package category for the transport of large quantities of radioactive material by air. This new package category was incorporated into the International Civil Aviation Organization (ICAO), Technical Instructions for the Safe Transport of Dangerous Goods by Air [2] and the International Air Transport Association (IATA), Dangerous Goods Regulations [3]. IATA implemented the provisions and requirements set in the IAEA's TS-R-1 regulations on July 1, 2001. The implementation of these regulations has made the air transport of these sources impractical.

This paper explores the Type C requirements and their applicability to the shipment of high activity sealed sources. It discusses the evolution of the requirements, addresses how one might design a Type C package for Cobalt 60 and assesses the issues and alternatives associated with the change in regulations. It also describes some practical problems associated with marine and road transport for these types of packages.

The Type C Requirements

Paragraph 416 of the IAEA TS-R-1 [1], states, "Type B(U) and Type B(M) packages, if transported by air, shall meet the requirements of paragraph 415 and shall not contain activities greater than the following:

- (a) for low dispersible radioactive material as authorized for the package design as specified in the certificate of approval,
- (b) for special form radioactive material -3000 A_1 or $100\ 000 \text{ A}_2$, whichever is the lower; or
- (c) for all other radioactive material -3000 A_2 ."

Table I, of the regulations [1] indicates that, for Cobalt 60, the A1 and A2 values are 400 GBq. Therefore the maximum activity for a Type B(U) package transported by air is 1200 TBq.

Typical shipments of high activity Cobalt 60 sources include packages loaded to 7.4 PBq. Typical irradiator sources have an activity of 370 TBq. Therefore, Type B(U) packages shipped by air are now limited to about three radioactive sources per package with a total package activity of about 1/6 of current package capacity.

Evolution of the Type C Package

During the revision cycle for the IAEA Regulations ST-1 for the Safe Transport of Radioactive Material it was suggested that additional performance criteria be added to the packages for shipment of plutonium by air. These additional requirements were initially based on the United States Regulatory Commission (USNRC) 10 CFR 71.64 and 10 CFR 71.74 requirements for shipment of plutonium. Through discussions based on the hazards of various radionuclides, it was then determined that these additional requirements for air transport of plutonium should be extended to all other radionuclides. Subsequent meetings developed the Type C performance criteria.

At the final Technical Committee Meeting for the St-1 Regulations held in Vienna, it was felt by most member states that the new Type "C" package requirements would only affect a handful of shipments and mostly plutonium shipments.

Following the creation of the Type "C" package category the fuel cycle industry indicated that the material that they were shipping was so non-dispersible that it would not require the additional safety requirements prescribed for Type "C" packages. The proposed regulations were modified to allow higher activities to be shipped in the current package design if the contents met the requirements for Low Dispersable Radioactive Material. (LDRM)

Cobalt 60 Transport Packages

Figure 1 shows a typical transport package. The MDS Nordion F-168 package design is commonly used for shipments of up to 7.4 PBq of Cobalt 60. The contents are normally Special Form Radioactive Material sealed sources, with activities of approximately 370 TBq. The sources meet the ISO 2919 performance classification, E65646 and are secured in a cavity. The cavity is

approximately 160 mm in diameter and it 500 mm in height. Shielding consists of approximately 270 mm of lead.

The main shield is surrounded by fins that dissipate heat during the normal conditions of transport and also provide impact protection during the Type B(U) mechanical tests. The fins are surrounded by a fireshield that protects the shielding and contents during the Type B(U) thermal test.

This package design has been in use for many years. MDS Nordion has shipped approximately 70,000 sealed sources and over 500 million curies (20,000 PBq) of Cobalt 60 have been shipped safely throughout the world. There have been no incidents resulting in the loss of shielding or containment in over 40 years.

Building a Type "C" Package

The useful life of a Cobalt 60 source can exceed 20 years and the large installed base of Cobalt 60 sources makes it necessary to maintain existing or greater package cavity dimensions. Lead is the preferred material for shielding because of its relatively low cost, ease of installation and other operational properties. The gamma processing industry operations are best suited to package capacities of 200 kCi or greater. These constraints fix the external dimensions of the shield. The design of the impact and thermal protection is the remaining challenge.

The most significant challenges related to the design of a Type C package are the requirements to survive the impact and enhanced thermal tests. Many approaches to the design of impact limiters have been successfully applied to Type B(U) packages. For this case study, the concept of extending the fins was explored. However, the arguments presented are equally applicable to other impact limiter designs.

The Type C impact test requires the dissipation of about 50 times more energy than the Type B(U) mechanical test. Normally, the plastic deformation of the metal impact limiters is calculated to establish the amount of impact protection required. For this example, a highly simplified approach is used. An average compressive strength of the cushion is assumed and the size of the cushion required to absorb the Type C impact energy is calculated.

Typically, metal fins are used as impact protection in these kinds of package designs. Fins are about 100 mm in length. Under drop test conditions, the fins deform as shown in Figure 2. Let us assume that the deformation is half the fin height, or 50 mm.

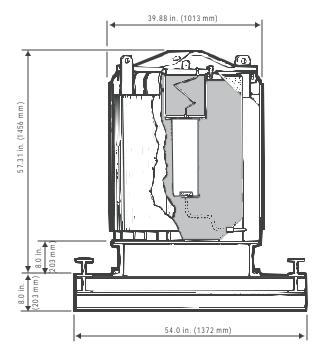




Figure 1. F-168 Transport Package

Figure 2. Typical Fin Deformation

The energy absorbed in the cushion is equal to the product of its average compressive strength and the crushed volume. For a typical 5500 kg package, the 9 meter drop test requires the absorption about 500,000 Nm of energy. In an upright drop orientation, the area of a typical crush front is about 0.75 m². Thus, if the observed crush is 50 mm, the average compressive strength of the impact protection must be about 13 MPa.

Since 50 times more impact energy must be absorbed, modifications to the fins are required. Let us assume that improved materials, thicker fins and other improvements in geometry enable the average compressive strength to be increased by a factor of seven to 90 MPa. Unfortunately, this also increases the inertial load to the package by a factor of 7, resulting in higher inertial loads during the accident conditions of transport.

Since we have increased the required energy absorption by a factor of 50, and increased the crush strength by a factor of 7, the new crush depth will be $50 \text{ mm} \cdot 50/7 = 350 \text{ mm}$. Allowing 50 mm for bottom out, yields a fin height of 400 mm.

Applying similar calculations to the remaining drop orientations would likely increase the required height of the fin. However, for this example, let us assume 400 mm of impact protection is required in all orientations.

Given a cavity 166 mm in diameter and 500 mm high, 270 mm of shielding and 400 mm of fin, the resulting external package dimensions would be 1500 mm diameter x 1840 mm. These dimensions

are incompatible with many existing irradiator facilities and handling techniques. They also add 1000 kg, or about 20%, to the weight of the package.

In addition to these structural modifications, changes must also be made to the thermal protection as the enhanced fire test is twice as long as the Type B(U) fire test. Insulation cannot be installed between the impact protection and the radiation shield because of the heat generated by the contents. 7.4 PBq of Cobalt 60 generates in excess of 3000 W. Too much insulation would cause the shielding around the cavity to melt due to the heat of the contents. This limits placement of insulation to the outside of the impact protection. There is a delicate balance to be maintained. The high heat output of the sources combined with the enhanced fire test duration makes the design of the thermal protection a significant challenge. It is not clear if this could be achieved, or if a successful design could be licensed

In order to resolve this problem, alternative materials could be used for shielding. Tungsten and depleted uranium are obvious candidates. Unfortunately their costs and characteristics make them impractical for this package design. These materials would decrease the external dimensions of the package and therefore decrease the amount of energy that needs to be absorbed during the impact test. However, the corresponding decrease in weight would be far less than the 50 fold increase in impact energy.

It is estimated that the cost of designing a new Type C package for 7.4 PBq of Cobalt 60, the manufacture of prototypes, full scale testing, licensing and the manufacture of a fleet of packages would be approximately two million dollars. As a relatively small number of packages are transported by air, the return associated with this investment would not merit the cost.

Other Options

MDS Nordion is committed to servicing the gamma processing industry. Since designing a Type C package for Cobalt 60 is not practical, other means must be considered to service the sterilization industry. These include qualifying the Cobalt 60 as LDRM, shipping Type C quantities by air using multiple Type B(U) packages and obtaining special arrangements for transport.

LDRM for Cobalt 60

Although it is possible to manufacture a source that would meet the test requirements for low dispersible radioactive material, section 605 (a) of the IAEA TS-R-1 regulations [1] limits the radiation level at 3 m from the unshielded radioactive material, to 10 mSv/h. Assuming a typical activity of 370 TBq, the radiation level at 3 metres would be 15 Sv/h, which greatly exceeds the 10 mSv/h limit. Therefore, the high radiation level from the sealed source makes it impossible to certify it as low dispersible radioactive material. Hence, this option is not applicable.

Multiple Type B(U)-85 Packages

Shipment by air of Cobalt 60 in quantities not exceeding 1200 TBq (32400 Ci), can be performed using a Type B(U)-85 package transporting three to four sealed irradiator sources. For the typical 7.4 PBq shipment, six Type B(U)-85 packages would be required. Although six F-168 packages

can be transported in a Boeing 747, a typical plane would load less than six and would necessitate separating the shipment into two or more planes.

Neglecting the cost of purchasing five additional packages the average cost of shipping a single F-168 by air is \$30,000. Hence, shipping six F-168 containers by air would represent an additional \$150,000 per single shipment. For the average of 10 shipments per year, the annual increase in cost is almost one and a half million dollars.

From a practical perspective, this option would not affect the risk associated with the shipment. The risk of an activity is determined by multiplying the consequence times the probability of the event happening. Assuming that all six type B(U) packages are transported on the same plane the probability of an accident has not changed. Since the total activity has been divided into six smaller quantities per package, the potential consequence of an accident has changed marginally. Therefore, the increased shipment cost has not decreased the risk associated with the air transport of 7.4 PBq of Cobalt 60.

Special Arrangements under the IAEA and IATA Regulations

For shipments that do not satisfy all the applicable requirements of the IAEA regulations a Special Arrangement Certificate can be obtained. A similar provision for exemption from the regulations is found in the Section 1.2.5 of the IATA regulations.[3] An exemption to the regulations is only granted in cases of extreme urgency or when other forms of transport are inappropriate or full compliance with the prescribed requirements is contrary to the public interest.. The exemption must be granted by the States concerned including points of origin, transit, overflight and destination.

Special Arrangement Certificates have typically been issued by competent authorities for the return of spent sources or other radioactive materials, which, if left in the current environment, would present a greater hazard to the environment and public health. Although the return of spent sources would qualify, it is unlikely that a Special Arrangement Certificate would be issued to allow for a commercial shipment of new sources. In addition, a Special Arrangement Certificate requires approval from all competent authorities affected by the transport.

It is foreseeable for a competent authority without an interest in the shipment to disallow transit or overflight. Furthermore, significant delays can be expected if multiple Special Arrangement Certificates are required in multiple jurisdictions.

Logistics Issues with Marine and Road Transport

In recent years, MDS Nordion has made approximately 10 shipments annually by air. By removing the air transport route, shipments outside Canada and the United States (USA) must now be done by marine transport. This becomes challenging as very few shipping lines accept radioactive material. The transport of large Type B(U) packages represent less than 1% of a shipping line business and incurs a large regulatory and insurance burden. Some shipping lines do not accept Class 7 goods.

Many airlines routinely transport radioactive material. The short half lives of many medical isotopes require them to be shipped by air. Volumes are also high. As a result, air carriers are familiar with the transport of class 7 goods and have developed the infrastructure to support them.

In addition to the shipping line restrictions, regulatory approval may be required for Type B(U)-85 packages that transit through various ports and countries enroute to the final destination. This regulatory burden further hinders the efficient transport of packages.

Very few shipping lines will transport radioactive material, consequently there are countries that are therefore not serviced by any shipping lines. Consider the following examples:

- 1. There are currently no shipping lines that will allow the transport of radioactive material into a Mexican port. In addition, Mexico will not allow USA road carriers into Mexico and the USA will not allow Mexican carriers into the USA. As a result, the transport packages have to be transferred from a USA trailer to a Mexican trailer at the border or the trailer has to be hitched to a Mexican tractor at the border. Air transport easily resolves this issue.
- 2. There are no shipping lines that will transport Class 7 goods into the Mediterranean Sea. Therefore transport of Cobalt 60 to countries such as Italy is through other European ports by road across Europe.
- 3. Today there is only one shipping line and one vessel that will transport radioactive material between South America and North America. This vessel transits from South America to North America every month. Typically the vessel is in port for less than 48 hours. Therefore the logistic issues involved with the delivery to the port are critical. Often, in addition to the regular shipment notification required by the regulations [1], some countries also require the Canadian B(U) Certificate to be endorsed by a national competent authority, or require special permission to transit through a port. Air shipments would allow these countries to be bypassed.
- 4. Marine shipments may also be at risk due to commercial changes. In a similar example, a shipping line that accepted radioactive materials for direct transport between South America and North America was purchased by another shipping line that did not accept radioactive material. As a result of the acquisition, it became impossible to directly ship between South America and North America. The only means of transporting class 7 goods was by first shipping the Cobalt 60 to Europe and then back to Canada. This has not only added to the cost of the shipment but has also increased the transit time considerably. In addition, since the transport package is now transiting through Europe, an ADR [5] approval of the 1985 type B(U) package certificate was required.
- 5. In certain countries where marine transport is possible the road infrastructure is not adequate to allow the transport by road of Cobalt 60 from the port to the irradiator facility. Shipment weights often exceed the capacity of the roads. This makes delivery and retrieval of Cobalt 60 from certain locations extremely challenging.

Conclusion

Since the implementation of the Type "C" requirement in the IATA and ICAO regulations on July 1, 2001, MDS Nordion has not been required to ship to areas were air transport is the only shipping route available. MDS Nordion has received requests for shipment to certain areas where marine transport is not possible because shipping lines do transport radioactive material to this area. MDS Nordion has been investigating, with freight forwarders other possible shipping routes using a creative approach of marine and road transport. The logistic difficulties involved and the increase in handling, storage and transit time will result in increase cost, shipment duration and radiation exposure to workers. The longer routes also increase the probability of an accident.

The cost of changing any regulations should be outweighed by the benefit gained from this change. The costs associated with the design and manufacture of a Type C package are prohibitive. The alternatives of multiple Type B(U) packages or Special Arrangements are also costly or impractical.

Operational experience has shown that shipment of Cobalt 60 by air is safe. The reduction in risk associated with the change in the air transport regulations has not been clearly shown. Consequently, costs and other practical considerations outweigh any benefits associated with this change in regulations.

References

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