From: "CHATEAUVERT, Carol" <Carol.CHATEAUVERT@mdsinc.com>
To: <nrcrep@nrc.gov>
Date: Wed, Aug 15, 2007 10:12 AM
Subject: Response from G. Malkoske, Chairman, GIPA on Reg. for the Safe Transport of Radioactive Material; Solicitation of Issue Proposals

7/10/07
72FR37471
(3)

Attention: Mr. Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, USNRC

Dear Mr. Lesar:

Please note the attached letter from Mr. Grant Malkoske, Chairman, Gamma Industry Processing Alliance, on behalf of GIPA.

Subject: Regulations for the Safe Transport of Radioactive Material; Solicitation of Issue Proposals

The letter and attachment is also being sent via courier to you today.

Please advise if you have any problems opening the attachment.

Thank you.

Carol Chateauvert
Executive Administrative Assistant
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From: "CHATEAUVERT, Carol" <Carol.CHATEAUVERT@mdsinc.com>

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Safe. Secure. Vital.

GIPA
Gamma Industry Processing Alliance

August 15, 2007

Mr. Michael T. Lesar
Chief
Rulemaking, Directives and Editing Branch
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission
Washington, DC
20555-0001

RE: Regulations for the Safe Transport of Radioactive Material; Solicitation of Issue Proposals

Dear Mr. Lesar:

The attached comments are as a result of the United States Nuclear Regulatory Commission (USNRC) and the United States Department of Transportation (USDOT) soliciting proposed issues or identified problems with the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material. These comments are submitted on behalf of the Gamma Industry Processing Alliance (GIPA).

GIPA represents gamma processing industry leaders. We advocate the development of responsible regulations that enhance the safe and secure management of cobalt-60 sources and related irradiation processing facilities. We are committed to the prompt dissemination of accurate information about this beneficial and vital technology. We believe in acting together to quickly deal with emerging issues that affect the future beneficial applications of gamma processing.

Radioisotopes are safely and securely transported under strict regulatory controls to ensure the material benefits people worldwide. One such product is cobalt-60, an essential radioisotope that prevents the spread of disease and infection. However, air shipments of this material are being prohibited since the implementation of the International Atomic Energy Agency (IAEA), Safety Standards Series No.TS-R-1 (ST-1, Revised), "Regulations for the Safe Transport of Radioactive Material," 1996 Edition (Revised) in the International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) requirements in July 2001.

As explained on the attached comments, GIPA recommends that the Low Dispersible Radioactive Material (LDRM) radiation level limits specified in paragraph 605 of the IAEA regulations be re-evaluated to enable air shipments of Cobalt-60 for gamma sterilization and other processing applications.

We would be pleased to discuss this further with you at your convenience.

Yours truly,

Grant Malkoske
Chairman
Gamma Industry Processing Alliance

Attachment to GIPA letter of August 15, 2007 to USNRC on "Regulations for the Safe Transport of Radioactive Material; Solicitation of Issue Proposals"

Radioisotopes are safely and securely transported under strict regulatory controls to ensure the material benefits people worldwide. One such product is cobalt-60, an essential radioisotope that prevents the spread of disease and infection. However, air shipments of this material are being prohibited since the implementation of the International Atomic Energy Agency (IAEA), Safety Standards Series No.TS-R-1 (ST-1, Revised), "Regulations for the Safe Transport of Radioactive Material," 1996 Edition (Revised) in the International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) requirements in July 2001.

Over 40% of all disposable medical supplies are sterilized every year thanks to cobalt-60 shipments. This would include bandages, sutures and an estimated 80% of all surgeons' gloves (figure 1). Certain biological products can only be sterilized using this form of sterilization, notably serums and plasma, and sealed medical devices such as those used in endoscopic procedures (Figure 2). The irradiation process is also used to treat certain foods, such as eliminating microbes from many spices and to extend the shelf-life of foods (Figure 3).

Figure 1

Figure 2

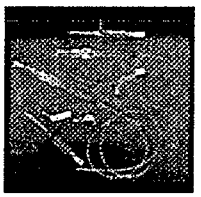

Figure 3

The effectiveness of cobalt-60 is due to its radioactivity – the energy it gives off is harnessed for healthcare, research, consumer and industrial purposes. For sterilization purposes, products can be irradiated after they are packaged and boxed which reduces the chance of products becoming re-contaminated. To treat cancer, a beam of radiation can be directly aimed at a certain tumours thus minimizing exposure of normal, healthy cells. Similar to receiving a dental x-ray, such uses do not make the individual, or material, radioactive.

Air transport is essential because most countries are importers of cobalt-60. Given that there are only a handful of cobalt-60 suppliers, most countries depend on the import of this material or on the final processed products sterilized by cobalt-60. In some cases cobalt-60 cannot be transported by marine transport. Therefore, this versatile material cannot be shipped to where it is needed. Yet the global demand for cobalt-60 to prevent and treat disease is growing. GIPA believes that suppliers and users need to have options available for the delivery of this vital material and to effectively manage around "denial of shipment" issues.

The Current Situation

Since the introduction of the Type C package category in the IAEA and then the ICAO and IATA requirements in July 2001, air shipment of large quantities of radioactive material has not been possible without obtaining exemptions. In the six years since the implementation of this package category, a Type C package has yet to be licensed by a competent authority or a Low Dispersible Radioactive Material (LDRM) certificate issued. Nonetheless, air shipments of large quantities of material have continued under ICAO exemptions issued by member states. Although some shipments of cobalt 60 have been done under exemption, the majority of these shipments done have been for fissile materials, which are shrouded with secrecy and therefore cannot be accurately reported.

There has been several papers written and published that address the problems and concern surrounding the transport of large quantities of radioactive material.

The problems associated with the design of a Type C package for the transport of Cobalt 60 has been addressed in Mr. M. Krzaniak & Mr. M.-A. Charette paper titled, "The Effects of Type C Packaging Regulations on the Shipment of High Activity Cobalt 60 Sources," presented at Packaging and Transportation of Radioactive Materials (PATRAM) 2001.

As a result the only alternative left is marine transport. The difficulty and problems associated with the transport of radioactive material by marine transport have been described in Mr. D. Rogers paper titled, "Transport of Gamma Sterilisation Sources," which was presented at the IAEA Safety of Transport of Radioactive Material Conference in July 2003. As indicated in the paper in some cases it is virtually impossible to transport cobalt 60 to certain irradiator sites.

There has been a paper written by Mr. P. Eyre titled, "Type B Activity Limits for Air Transport – (An Examination of Special Form and Non-special Form Limits)," which was presented at PATRAM 2004. This paper reviews the radiation level limits prescribed for LDRM sources.

Since July 2001 there has not been a design of a Type C package or of LDRM sources. However, shipment by air of this quantity of radioactive material has continued under ICAO exemptions issued by some member states. As such these new requirements have done nothing to increase the safety in transport but have prevent the efficient, safe and secure movement of large quantities of radioactive material for the sterilization of medical disposables.

Radiation Level for LDRM Sources

The regulations allow up to 3000 A_1 or 3000 A_2 of radioactive material in a Type B package when transported by air. The same Type B package however is only allowed to carry the approximate equivalent of A_1 of radioactive material when the material is Low Dispersible Radioactive Material due to the limitation on external dose rate in para 605 (a). This is inconsistent and the limit should be changed for this reason.

Limiting the external radiation level at 3 m from the unshielded low dispersible radioactive material to 10 mSv/h was to ensure that the potential external dose would be consistent with the potential consequences of severe accidents involving Industrial packages (see para. 521). However, as low dispersible radioactive material would be carried in a Type B package, in any given accident scenario the remaining shielding from the Type B packaging would be greater than that from an industrial package. This is because a Type B package is designed to withstand severe accidents whereas Industrial packages have only to be designed to withstand up to normal conditions of transport. Consequently, the limit on the dose rate from unshielded low dispersible radioactive material needs to be re-examined. For material that is not low dispersible radioactive material, up to 3000 A_1 or 3000 A_2 would be permitted in a Type B package. This represents a potential point source external dose rate approximately 3000 times higher than 10 mSv/h at 3 m. There is no reason to arbitrarily limit low dispersible radioactive material to a lower value, as it also would be carried in a Type B package. In addition, considering the maximum Type B package release estimated in IAEA-TECDOC-702 of 3%, the dose rate from 3 % of the potential 100 A_2 airborne releasable material would be significantly less than for a comparable Type B package carrying material that is not low dispersible radioactive material.

Consequently it is proposed that the limit on external dose rate should be removed in the 2009 changes to the transport regulations. Alternatively, the equivalent of the dose rate from 3000 A_1 of material, unshielded should be permitted for consistency.

Conclusion

Although the new requirements were implemented in July 2001, a Type C or LDRM approval has not yet been issued by a competent authority. Nonetheless air transport has continued with the aid of exemption under the ICAO regulations. There have been several papers written discussing the issue with building a Type C package and the problems associated with marine transport. There has also been issued raised with denial of shipment with marine transport. A paper has recently been written outlining the discrepancy in the regulations with the LDRM materials.

There is a need to re-evaluate the LDRM radiation level limits specified in paragraph 605 of the IAEA regulations in view of the discrepancy in the regulations, the issuance of exemption, the denial of marine transport and the use of this material to sterilize product for the benefit of human health.