DANGEROUS GOODS PANEL (DGP)

NINETEENTH MEETING

Montreal, 27 October to 7 November 2003

INFORMATION FROM THE IAEA CONCERNING A PROPOSED CHANGE TO THE REGULATORY REQUIREMENTS FOR AIR SHIPMENTS OF COBALT-60

(Presented by IAEA)

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BACKGROUND

The 1996 edition of the IAEA Regulations for the Safe Transport of Radioactive Material (Transport Regulations) introduced a variety of stricter requirements for air shipment of radioactive material. These stricter requirements became effective for international air transport through the ICAO Technical Instructions on 1 July 2001. These stricter requirements significantly affected some types of air shipments, in particular the air shipments of typical quantities of Co-60 sealed sources.

At the beginning of 2002 the IAEA started a review of its 1996 edition of the Transport Regulations by inviting proposals for changes. Four proposals were received concerning changes that would result in allowing the air shipments of the Co-60 sealed sources to resume. A working group at the September 2002 review panel meeting reviewed these four proposals and prepared a resulting proposed change for comments by member states. There was significant reluctance in plenary at the review panel meeting to accept this proposed change for further comments. However, at the request of several participants at the review panel meeting, including the ICAO representative, the review panel accepted the proposed change for further comments during a 120 day comment period. It was identified as proposed change 16. The Transport Safety Standards Committee (TRANSSC) at its March 2003 meeting endorsed that the proposed changes accepted by the review panel meeting should go out for 120 day comment. The comment period expired 15 September. Comments have been received.

The original four proposals for a change to the regulations affecting air shipments of Co-60, the resulting proposed change 16 and all the comments received on proposed change 16 are made available in this report for information. Any further comments from this ICAO DGP meeting will be made available to the next review panel meeting that will be held 10-14 November 2003 in Bonn.

Principal objective of proposed change: (Delete what does not apply)

- Necessary to provide adequate protection to health and safety of public and occupational workers
- Needed to improve implementation of the Regulations
- Necessary to improve implementation and harmonisation.

Topic of proposed change: **Revision to Type B contents limits for air transport.**

Justification for proposed change:

- **Intent: The primary intent of the introduction of the Type C category was to afford the public a level of protection that took account of the increased impact speeds associated with air transport. The study did not however take account of the fact that gamma radioisotopes are transported in heavy, robust package designs that are intrinsically more likely to be cushioned than damaged by the aircraft structure and other cargo. Also sudden stop impacts are only associated with high angle aircraft/ground impacts which invariably result in a crater which affords considerable self shielding. Low angle impacts on the other hand result in the kinetic energy being dissipated over a much longer period of time affording the package a far greater chance of survival. These facts were not taken into account in the original modelling. This proposal does not seek to reduce standards but rather to maintain them as they are and to refine the model.**
- **Effect: The enforced removal of the option of air transport for gamma sterilisation source shipments has led to:**
  - **A substantial increase in worker and public dose uptake due to increased duration of shipments and much longer road element.**
  - **Curtailment of supplies (and hence a loss of an indigenous ability to sterilise foodstuffs and essential medical equipment) to an increasing number of countries due to shipping line and/or port refusal to handle Class 7 goods. This is leading inevitably to higher costs for these services when they have to be sourced abroad and consequently a reduction in funding available for other healthcare services.**
  - **A reduction in security, leading to an increased risk to public safety, during shipment due to increased duration and number of transhipments and generally lower security standards in the marine industry.**
- **Consistency: The application of Type C requirements to fissile material only would be consistent with the IAEA's approach to public perception (as evidenced by the fire test requirement for uranium hexafluoride, justified by the public's heightened awareness of military/reactor nuclear materials).**
- **Harmonisation: The secondary intent of the introduction of the Type C category was to encourage harmonisation, particularly with the US which already has a similar requirement but only for plutonium. The concept of Type C for all nuclides has however been rejected by the US as the perceived costs do not justify the benefit.**
- **Costs: There are no costs associated with this proposal.**
- **Benefit: The ability to transport Special Form Co^{60} by air in Type B(U) packaging would reduce worker and public dose uptake, allow several countries to maintain indigenous sterilisation services and allow increased security during transport. The restriction of Type C to fissile materials will have much wider acceptance and would be implemented with a minimum of national variation.**

Paragraphs affected and proposed text change to regulatory text in TS-R-1 (ST-1, Rev.) **416: Insert the word "fissile" i.e.** **(b) for special form *fissile* material -** **(c) for all other *fissile* radioactive material**	Paragraphs affected and proposed text change to advisory material in TS-G-1.1 416.1. For Type B(U) and Type B(M) packages to be transported by air the contents limits are further restricted to the lower of 3000 A1 or 100 000 A2 for **fissile** special form material and 3000 A2 for all other **fissile** radioactive material. 416.2 The 3000 A2 limit for non-special form material was established taking into account risk analysis work by Hubert et al. [9] concerning Type B package performance in air transport accidents. It is also the threshold quantity for which shipment approval of Type B(M) packages is required. 416.3. With regard to the radioactive contents limit for special form radioactive material, it follows from the Q system that 3000 A1 was adopted as the radioactive content limit for such material in parallel to the 3000 A2 radioactive contents limit. However, for certain alpha emitters the ratio A1 to A2 can be as high and so an associated value of 100 000 A2 was taken as am additional limit. 416.4. Radioactive material in a non-dispersible form or sealed in a strong metallic capsule presents a minimal contamination hazard, although the direct radiation hazard still exists. Additional protection provided by the special form definition is sufficient to ship special form material by air in a Type B(U) package up to an activity of 3000 A1 but not more than 100 000 A2 of the special form nuclide. French studies indicated that some special form material approved under current standards may retain its containment function under test conditions for air accidents [9].
Proposal for transitional arrangements, if needed: **None needed.**	
Applicable reference documents (if needed): **None.**	
No. of additional sheets of supporting documentation attached (in electronic form please): **None.**	
Description of problem to be addressed: **The possible exposure of people as a result of an extremely rare event has resulted in a definite increase in the exposure of workers and public on a routine basis. It is suggested that the limits in 416 are not justified in terms of safety (they are too low for gamma emitters).** Summary of proposed solution to the Problem: **Relate the limit to fissile material – the material of primary concern.**	

Principal objective of proposed change: (Delete what does not apply)

- Necessary to provide adequate protection to health and safety of public and occupational workers
- Necessary to improve implementation and harmonisation.

Topic of proposed change:

Revision to Type B contents limits for air transport.

Justification for proposed change:

- **Intent: The primary intent of the introduction of the Type C category was to afford the public a level of protection that took account of the increased impact speeds associated with air transport. The study did not however take account of the fact that gamma radioisotopes are transported in heavy, robust package designs that are intrinsically more likely to be cushioned than damaged by the aircraft structure and other cargo. Also sudden stop impacts are only associated with high angle aircraft/ground impacts which invariably result in a crater which affords considerable self shielding. Low angle impacts on the other hand result in the kinetic energy being dissipated over a much longer period of time affording the package a far greater chance of survival. These facts were not taken into account in the original modelling. This proposal does not seek to reduce standards but rather to maintain them as they are and to refine the model.**
- **Effect: The enforced removal of the option of air transport for gamma sterilisation source shipments has led to:**
    - **A substantial increase in worker and public dose uptake due to increased duration of shipments (weeks, sometimes months, instead of days), much longer road elements (sometimes trans-continental) and far greater handling, trans-shipment and storage.**
    - **The curtailment of supplies (and hence indigenous ability to sterilise foodstuffs and essential medical equipment) to an increasing number of countries due to shipping line and/or port refusal to handle Class 7 goods. This is leading inevitably to higher costs for these services when they have to be sourced abroad and consequently a reduction in funding available for other healthcare services.**
    - **A reduction in security, and hence increased risk to public safety, during shipment due to the increased duration, the greater number of transhipments and the generally lower security standards in the marine industry.**
- **Consistency: The application of Type C requirements to fissile material only would be consistent with the IAEA's approach to public perception (as evidenced by the fire test requirement for uranium hexafluoride, justified by the public's heightened awareness of military/reactor nuclear materials).**
- **Harmonisation: The secondary intent of the introduction of the Type C category was to encourage harmonisation, particularly with the US which already has a similar requirement but only for plutonium. The concept of Type C for all nuclides has however been rejected by the US as the perceived costs do not justify the benefit.**
- **Costs: There are no costs associated with this proposal.**
- **Benefit: The ability to transport Special Form Co60 by air in Type B(U) packaging would reduce worker and public dose uptake, allow several countries to maintain indigenous**

sterilisation services and provide increased security during transport. The restriction of Type C to Plutonium will have much wider acceptance and would be implemented with a minimum of national variation.	
Paragraphs affected and proposed text change to regulatory text in TS-R-1 (ST-1, Rev.) • **416. Type B(U) and Type B(M) packages, if transported by air, shall meet the requirements of para. 415 and shall not contain Plutonium with a total activity greater than the following:** • **(c) for all other Plutonium**	Paragraphs affected and proposed text change to advisory material in TS-G-1.1 416.1. For Type B(U) and Type B(M) packages to be transported by air the contents limits are further restricted to the lower of 3000 A1 or 100 000 A2 for **Plutonium** as special form material and 3000 A2 for all other **Plutonium**. 416.2 The 3000 A2 limit for non-special form material was established taking into account risk analysis work by Hubert et al. [9] concerning Type B package performance in air transport accidents. It is also the threshold quantity for which shipment approval of Type B(M) packages is required. 416.3. With regard to the radioactive contents limit for special form radioactive material, it follows from the Q system that 3000 A1 was adopted as the radioactive content limit for such material in parallel to the 3000 A2 radioactive contents limit. However, for certain alpha emitters the ratio A1 to A2 can be as high and so an associated value of 100 000 A2 was taken as am additional limit. 416.4. Radioactive material in a non-dispersible form or sealed in a strong metallic capsule presents a minimal contamination hazard, although the direct radiation hazard still exists. Additional protection provided by the special form definition is sufficient to ship special form material by air in a Type B(U) package up to an activity of 3000 A1 but not more than 100 000 A2 of the special form nuclide. French studies indicated that some special form material approved under current standards may retain its containment function under test conditions for air accidents [9].
Proposal for transitional arrangements, if needed: **None needed.**	
Applicable reference documents (if needed): **None.**	
No. of additional sheets of supporting documentation attached (in electronic form please): **None.**	
Description of problem to be addressed: **The possible exposure of people as a result of an extremely rare event has resulted in definite increase in exposure of workers and public on a routine basis. It is suggested that the limits in 416 are not justified in terms of safety (they are too low for gamma emitters).**	
Summary of proposed solution to the Problem: **Relate the limit to Plutonium – the material of primary concern.**	

Principal objective of proposed change: (Delete what does not apply)

- Required for consistency within the Regulations.
- Necessary to provide adequate protection to health and safety of public and occupational workers

Topic of proposed change: **Revision to LDRM requirements.**

Justification for proposed change:

- **Inconsistency: The unshielded radiation level requirement is not supported by a safety comparison with the Special Form limit in an air transported Type B(U) package or by the definition in TS-R-1:**
  - **The unshielded radiation level criterion for LDRM in para 605(a) is 10 mSv/h at 3m, i.e. the same as for determining the A_1 value for the nuclide. The only value in qualifying a source as LDRM is to air transport more than 3000 A_1 (except that the radiation criterion limits gamma emitting LDRM to A_1). This is inconsistent with the Type B Special Form package release potential for air transport, set at 3000 A_1. LDRM has a far higher safety qualification than Special Form Material and yet the allowable limit in an air transported Type B(U) package is 3000 times less than Special Form. The regulations are actively discouraging the adoption of the higher safety standard. The radiation limit should either be removed or be set at a level sufficiently higher than that obtained from 3000 A_1 to reflect the intrinsically higher safety of LDRM.**
  - **Para 225 of TS-R-1 defines LDRM as material "that has limited dispersibility". Radiation may only be emitted from a material, it cannot be dispersed.**
- **Effect: The inability to qualify gamma sources as LDRM closes the only possible option for continuing to transport Special Form Co^{60} sterilisation sources by air in Type B(U) packaging (Nordion have demonstrated it is not possible to develop Type C packages for such material (see below)). This has led directly to:**
  - **A substantial increase in worker and public dose uptake due to the increased duration of shipments (weeks, sometimes months, instead of days), much longer road elements (sometimes trans-continental) and increased handling, trans-shipment and storage frequency.**
  - **The curtailment of supplies (and hence indigenous ability to sterilise foodstuffs and essential medical equipment) to an increasing number of countries due to shipping line and/or port refusal to handle Class 7 goods. This is leading inevitably to higher costs for these services as they have to be sourced abroad and hence reduced funding available for other healthcare provision.**
  - **A decreased security, and hence increased risk to public safety, during shipment due to the increased duration, the greater number of transhipments and the generally lower security standards in the marine industry.**
- **Safety: In the unlikely event of an aircraft impact sufficient to rupture or melt a Type B(U) package none of the crew or passengers would survive and there would be no urgent need for the emergency services to get close. The emergency services would however be readily able to**

maintain a safe level of exposure by setting an appropriate stand-off distance or exclusion zone. Emergency services must be equipped with radiation monitors to attend any incident with a potential radiation hazard. As stand-off distance is determined by the radiation levels registered no change to current procedures would be necessary.

- **Cost: There are no costs associated with this proposal.**
- **Benefit: The ability to qualify Special Form Co^{60} as LDRM would allow sterilisation sources to be transported by air when necessary in Type B(U) packaging. This would reduce worker and public dose uptake, allow several countries to maintain indigenous sterilisation services and increase security during transport.**

Paragraphs affected and proposed text change to regulatory text in TS-R-1 (ST-1, Rev.)	Paragraphs affected and proposed text change to advisory material in TS-G-1.1
605(a) Delete paragraph.	**225.2 Delete "or exposures".** **605.1 Delete paragraph.**

Proposal for transitional arrangements, if needed: **None.**

Applicable reference documents (if needed):
The Effects of Type C Packaging Regulations on the Shipment of High Activity Cobalt 60 Sources" by Michael Krzaniak and Marc-Andre Charette, PATRAM 2001.

No. of additional sheets of supporting documentation attached (in electronic form please): **None.**

Description of problem to be addressed:
The basis for the LDRM dose criteria is one A_1. Compared with the permitted quantity of Special Form material (3000A_1) for air transport in a B(U) this is not only anomalous but it is actively discouraging the use of material to higher safety qualification.

Summary of proposed solution to the Problem:
Delete the exposure limits on LDRM.

PROPOSAL CANADA/02/02

Principal objective of proposed change: (Delete what does not apply)

- Necessary to provide adequate protection to health and safety of public and occupational workers
- Needed to improve implementation of the Regulations

Topic of proposed change:
Change the Type "C" requirements to apply to fissile materials and not all radioactive material.

Justification for proposed change:

The introduction of the new package type "C" was influenced by legislation passed in the United States of America in Public Law 94-74. This law prohibited the US Nuclear Regulatory Commission from licensing the air shipment of plutonium until a container had been designed and certified that would withstand the explosion and crash of a high-flying aircraft. The criteria for the design of a container for the air transport of plutonium were published in NUREG-0360. The intent of this regulation was to cover plutonium shipments by air and not all radioactive material shipment by air. At the final technical committee meeting for the ST-1 regulations, it was felt by most member states that the Type C package requirements would only affect a handful of shipments and mostly plutonium. This is not the case.

There has not been a demonstrated need for Type "C" packages for all radioactive material. The benefits do not outweigh the costs.

The requirements for Type "C" packages should be limited to the original intent of the regulations : fissile material and not all radioactive material. The attached paper titled, "The Effects of Type C Packaging Regulations on the Shipment of High Activity Cobalt 60 Sources" by Michael Krzaniak and Marc-Andre Charette, PATRAM 2001, explains that the Type "C" requirement is impractical for the transport of Cobalt 60 by air.

Paragraphs affected and proposed text change to regulatory text in TS-R-1 (ST-1, Rev.)	Paragraphs affected and proposed text change to advisory material in TS-G-1.1
Paragraph 416 add the word fissile in (b) and (c) 416 (b) for **fissile** special form radioactive material – 3000 A_1 or 100 000 A_2, whichever is the lower; or 416 (c) for all other **fissile** radioactive material – 3000 A_2.	

Proposal for transitional arrangements, if needed: None

Applicable reference documents (if needed):
The Effects of Type C Packaging Regulations on the Shipment of High Activity Cobalt 60 Sources" by Michael Krzaniak and Marc-Andre Charette, PATRAM 2001

No. of additional sheets of supporting documentation attached (in electronic form please): 8

Reference document

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

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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 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.

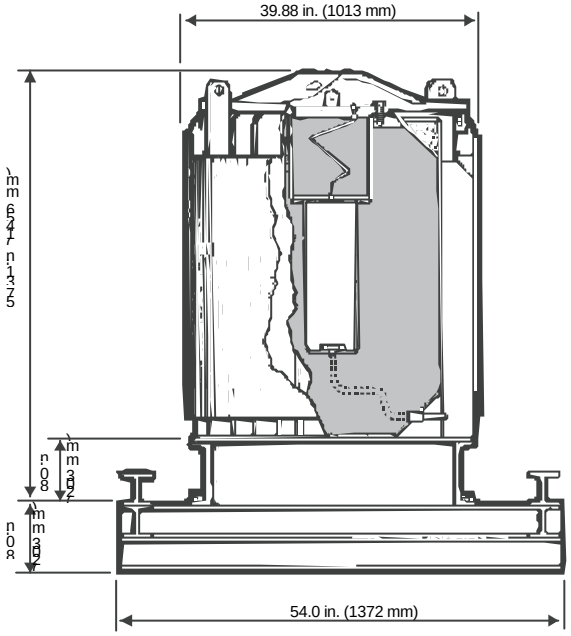

Figure 1. F-168 Transport Package

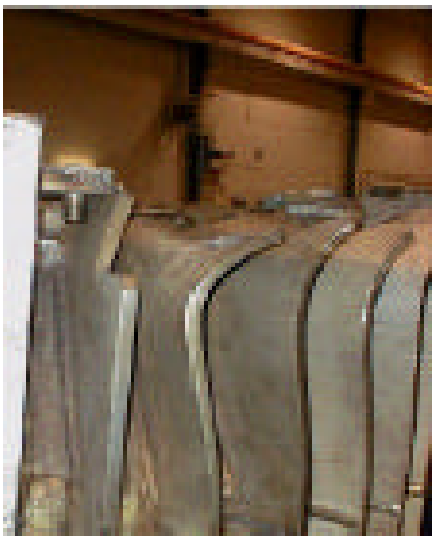

Figure 2. Typical Fin Deformation

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 m^2. 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 mm*50/7 = 350 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

1. International Atomic Energy Agency, Safety Standards Series Regulations No. TS-R-1 (ST-1 Revised), Regulations for the Safe Transport of Radioactive Material 1996 Edition (Revised).

2. International Civil Aviation Organization, Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2001-2002 Edition.

3. International Air Transport Association, Dangerous Goods Regulations, 42nd Edition, Effective 1 January 2001.

4. International Standard, ISO 2919:1999(E), Radiation protection – Sealed radioactive sources – General requirements and classification, Second edition 1999-02-15.

5. Economic Commission for Europe, Inland Transport Committee, European Agreement concerning the international carriage of dangerous goods by road (ADR) and protocol signature, 1 January 1999.

Proposed change 16

Proposed change 16 resulted from review of proposals UK/02/48, UK/02/49, UK/02/52 and CANADA/02/02 by the September 2002 Review Panel meeting.

Existing text in IAEA Transport Regulations	Proposed text (for comment)
416. *Type B(U)* and *Type B(M) packages*, if transported by air, shall meet the requirements of para. 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 A_2, whichever is the lower; or (c) for all other *radioactive material* — 3000 A_2.	416. *Type B(U)* and *Type B(M) packages*, if transported by air, shall meet the requirements of para. 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 Co-60 as *special form* – 30000 A_1 ;** (**c**) for **other** *special form radioactive material* — 3000 A_1 or 100 000 A_2, whichever is the lower; or (**d**) for all other *radioactive material* — 3000 A_2.

Comments received by IAEA on Proposed Change 16 concerning Co-60

2. Comment submitted by: Argentina.

4. Response to the Proposed Change (mark appropriate box):

- Agree subject to the amended Proposed Change in item 6 below:

X Reject

5. Rationale for response to the Proposed Change

In first instance, the idea of the proposed change to the 2003 Edition of the Regulations, TS-R-1, seems to be acceptable but the explanation for that inclusion appears to be inconsistent because of the same reasoning would be applicable for radionuclides other than Co-60. It is desirable to take into acount that a proposed change to be included should be consistent with a general requirement than a specific one. For this proposed change is not clear how to include only an exemption for Co-60 contents limit as special form radioactive material (SFRM) instead of limiting Type C packages for fissile materials only, and to allow that Type B(U) / B(M) packages containing all radionuclides as SFRM or as other forms can be transported by all modes (land, sea and air).

In accordance with Q System the calculation of A_1 / A_2 values for all radionuclides is carried out that once the A_1 / A_2 value was obtained the potential radiological risk involved is the same for the transport of A_1 or A_2 amount of Co-60, Ir-192, Pu-239, U-235, etc., and in addition consideration shall be made due to requirements for packages containing fissile material.

More or less, in 1985, at the very begining of the development of the idea of the inclusion of a new package, named Type C package, it was mainly related with the problem of the transport of fissile material by air. Then, it was additionally considered that Type C packages should be also applied for the transport by air of some radionuclides like Co-60. At the end of the deep analysis performed, it was concluded that TypeC packages must be applied for the transport by air of all radionuclides when their radioactive contents are greater than defined activities.

At the light of new technical evaluations as well as economic and comercial problems mainly related to the transport of high activities of Co-60, it seems to be considered that Type C packages would be used: a) only for the transport by air of fissile material in activities greater than determined values, or b) at least to apply the 30 000 A_1 limit value for all radionuclides and not to restrict it for Co-60 only.

6. Amended Proposed Change, if any

416. Type B(U) and Type B(M) packages, if transported by air, shall meet the requirements of para. 415 and shall not contain activities greater than the following:
(a) **for special form radioactive material or** for low dispersible radioactive material – as authorized for the package design as specified in the certificate of approval;
(b) for **fissile material as** special form radioactive material – 3000 A_1 or 100 000 A_2, whichever is the lower; or
(c) for all other **fissile material** – 3000 A_2.

2. Comment submitted by: Belgium
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change Even if the reality of some problems is recognized, a solution by nuclide specific provisions in the regulations is not a sound option. Action should be undertaken on another level to stop the ban on radioactive materials in the sea transport field. Severe air accidents under the current provisions with maximum quantities in type B packages could already present a huge challenge to emergency intervention.

2. Comment submitted by: **France**
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change The arguments are mainly based on a cost increase, compared to the transport practice meeting the previous regulation, but without any clear estimation of this cost increase. In addition, there is no estimation of the impact on safety. The impact on safety is however important, it was the actual justification of the 1985 to 1996 edition change of the regulations. Indeed emergency management would be hardly feasible in case of a crash of an airplane carrying a high activity cobalt 60 source in a package. The emergency response teams would be endangered by high dose rates exceeding 3 Sv/h at 10 m and 30 mSv/h at 100 m. The other argument on doses (indicating that the maritime transport time is too long and then, the doses received by the workers are more important than doses received in the case of a transport by air) is not acceptable because the ALARA principle has to be correctly and at any time applied with an appropriate organization of the work.

2. Comment submitted by: Germany
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change The proposal is unacceptable because a) it is inconsistent with the exemption limit of 3000 A_1/A_2 for **all** radionuclides which had been introduced and justified based on very detailed studies and extensive discussions during the 1996 Revision Process as an acceptable level for Type B packages in case of low probability and high consequence accidents in air transport, b) the proposed increase of the exemption limit by a factor of 10 will result in an increase of the consequences by a factor of 10 which will lead to unacceptable doses in case of accidents. This is inconsistent with the basic safety principles of the regulations to provide the same level of safety / protection for all modes of transport, that means for the air mode the same as for the surface modes! There is no justification provided in the proposal based on acceptance criteria (release, external radiation) under Type C accident conditions, and other transport arrangements by applying current regulations are possible.

2. Comment submitted by: Japan
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change Rationale (safety reason) for "Co-60 as special form – 30000A_1" is not clearly explained nor agreed. Therefore, the Regulation should not be changed.

2. Comment submitted by: NORWAY
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change There is no scientific basis for making an exception from the requirements regarding Type C packages for Co-60. Allowing greater amounts of Co-60 than for other radionuclides in Type B packages has purely economical and practical reasons, it is not based on scientific arguments which could not have been used to make similar exceptions for other radionuclides as well.

2. Comment submitted by: Russia
4. Response to the Proposed Change: Agree subject to the amended Proposed Change in item 5 below:
5. Rationale for response to the Proposed Change The item 416(d) of the Proposed Change to write as follows: "(d) for *radioactive materials,* other than *special form radioactive material* and *low dispersible radioactive material – 3000 A_2*. Rationale. More exact text including Co-60 in non special form as well. Rationale for the Proposed Change as a whole. As known the need for type C packages was based in many relations taking into account the social factors of any air accidents with radioactive material in spite of or opposite of real scientific radiation risk assessments of such accidents. For Co-60 sources we have another social factor namely very important social meaning of medical using of Co-60 sources that strongly depends on well-timed deliveries of such sources provided by air as the best. So in this case we have to take into account such social factors and can sacrifice by scientific exactness as well.

2. Comment submitted by: Spain
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change The justifications of the proposal considers the increase of economical costs and the difficulties to carry out the shipments through another modes of transport, but the arguments don't include a Safety Analysis that justify the exception of the requirement exclusively for the Co-60. A safety evaluation should be required to prove that the transport of an activity of Co-60 up to 30000 A_1 in a Type B(U) package don't lead to unacceptable risks in case of an accident by air.

2. Comment submitted by: Sweden
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change There is no scientific basis for making an exception from the requirements regarding Type C packages for one radionuclide (Co-60).

2. Comment submitted by: Switzerland
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change The technical evidence available to back this proposal should be reviewed in detail, e.g. at the TCM of November 2003, before an exception is made for this nuclide.

2. Comment submitted by: USA
4. Response to the Proposed Change: Reject
5. Rationale for response to the Proposed Change Specific isotope exemptions based on operational expediency should not be granted, as this contradicts generic approach to Type C standards. Note that multiple Type B package air shipments appear to be a feasible alternative.