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DANGEROUS GOODS PANEL (DGP)

MEETING OF THE WORKING GROUP OF THE WHOLE

Abu Dhabi, 4 to 8 October 2004

OVERVIEW ON DENIAL OF RADIOACTIVE MATERIAL SHIPMENTS

(Presented by J. Code)

SUMMARY

Increasingly, shippers of radioactive (Class 7) materials are facing challenges in getting products transported by air. "Denial of shipment" refers to policies and practices which delay or outright deny the shipment of radioactive material, notably medical isotopes.

This situation has been evolving for several years and has largely gone undocumented. However, manufacturers of medical isotopes have more recently identified the trend and the increasing number of airlines that do not accept Class 7 goods outright or have restrictive practices which delay or restrict medical isotope shipments. These practices can disrupt their use in diagnosing and treating disease. Short-lived medical isotopes require immediate delivery as they are perishable. Shipment denials, and even delays, can affect the use of medical procedures in emergency rooms and hospitals.

The nature of the global supply network is that there are very few suppliers of such radioisotopes in the world and most countries are importers of this material. Therefore, international air transport of short-lived medical isotopes is crucial to meeting global requirements.

Nuclear Medicine

Nuclear medicine relies on the energy emitted by radioactive atoms to reveal physiological or biochemical functions in the body. It is an excellent way to diagnose disease and radiation is also widely used to treat cancer. An estimated 20 million nuclear medicine procedures are conducted every year using medical isotopes.

There are some 100 diagnostic applications of this technology. Nuclear medicine scans show, for instance, the rapid spread of cancer to the bones before it gives symptoms or shows on an X-ray. This is critical for patients awaiting surgery, chemotherapy or radiation treatment as they require accurate staging of their disease to determine the appropriate treatment course. Nuclear medicine is used extensively in cardiology, such as determining the severity of heart disease. The procedure of scanning the heart is less

invasive and risky as using angiograms which requires a catheter. As well, nuclear medicine is relied upon to scan the lungs for blood clots. Lung scans are critical to post-operative care. Following surgery, one of the body's reactions is to develop blood clots and diagnosis and urgent care is required.

Nuclear medicine includes the treatment of cancer. There are a variety of ways of doing so including inserting radioactive "seeds" directly into a tumour, such as for prostate and cervical cancer. New cancer therapies are also being developed by delivering radiation at the molecular or cellular level. Such treatments for liver cancer, brain cancer and non-Hodgkin's lymphoma are minimizing impact on healthy cells, reducing side effects and improving patient care. Some of these new therapies are known as "radioimmunotherapy" which was first approved for use in 2002 for non-Hodgkin's lymphoma, a blood-borne cancer.

Transportation & Packages

Transportation logistics are absolutely critical to shipping medical isotopes mainly because many of these products have short half-lives and most countries are importers of this material. These highly perishable products require expeditious delivery because they decay quickly are used with days, even hours, of delivery. For instance, iodine-123 has a half-life of 13 hours – meaning that every hour of delay results in a 5% product loss. Shipping delays lessen the utility of the product because it provides a poorer image quality for diagnosis, can require more product to do the same job and can lead to less patient throughput. Or, the product becomes totally unusable.

Medical isotopes are shipped in type B(U) or type A packages for daily transport on passenger, cargo or charter aircraft. The amount of actual radioactive material actually transported is very small; it can either be an individual pharmaceutical formulation for one patient or the package can contain a vial with some 150 ml of solution.

Packages, particularly type B(U), are robust and are designed to be tested under severe conditions: impact, puncture, thermal and immersion tests – to test shielding, containment. It has been noted that: "Over several decades of transport, there has never been an in-transit accident with serious human health, economic or environmental consequences attributable to the radioactive nature of the goods." (IAEA International Conference on the Safety of Transport of Radioactive Material, 2003)

Essentially, shipments of nuclear medicine products has an overall excellent history of safe transport. These products can be, and are, safely transported by air when done in compliance with ICAO and IATA requirements.

Denials of Shipments

Specific airlines in a number of regions have stopped transporting radioactive material altogether.

Moreover, there are cases where airlines do not ship on certain routes; one Canadian carrier, for instance, will not ship to one specific country due to additional cost of meeting regulatory requirements to handle Class 7 goods. Without explicitly banning the carrying of Class 7, airline policies can, in practice, prevent shipments. One U.S. airline does not allow the total sum of transport indices (TI) to exceed 6 on a passenger aircraft even though the regulations allow for a total TI of 50. Pilot refusals can cause medical isotopes to be bumped from a flight because animals have been loaded onto the aircraft. This can postpone shipments to the next day – undermining its usefulness. Such interventions occur even though the transport of animals and Class 7 materials is safe and permitted (pursuant to section 2.9.6.3, ICAO Technical Instructions).

The apparent reasons for denials occurring are varied, although the increased regulatory burden, and lack of international harmonization of requirements, is regarded by airlines as a significant disincentive to carry this material. Radioactive material is often treated differently than other dangerous goods which results in additional regulatory, administrative and training burdens on carriers of Class 7 materials. Moreover, there can be a lack of understanding of the nature of this material, which affects airline policy, pilot and loading decisions. A general increased sensitivity to handling radioactive material is also a contributing factor. Overall, economic considerations driven largely from regulatory burdens and complications appear to be the major reason for denials.

Working in Partnership

In short, the world depends on the shipment of medical isotopes by air for the beneficial uses of nuclear technology to diagnose and treat disease.

ICAO can play a meaningful role in helping to address this evolving situation and potentially serious issue. It can support other international efforts now underway to address the matter, notably a process developed by the IAEA. ICAO can also contribute to communication and education efforts to ensure harmonized application of regulatory standards so that additional requirements do not impede shipments. ICAO can help to ensure that required training to handle Class 7 is efficient. There may also be other ways for ICAO to facilitate acceptance of medical isotopes in the air mode.

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Presentation to the International Civil Aviation Authority

Facilitating the Acceptance of Medical Isotope Shipments

October 4, 2004

International air transport is critical

- Small number of medical isotope producers serve bulk of world market
- Most countries are importers of medical isotopes
- Short-lived medical isotopes require immediate shipment (usually by air)
- Patients and physicians depend on reliable and timely delivery of medical isotopes every day
- Airline policy and practices are increasingly preventing the shipment of Class 7 materials

Diagnosing & treating disease

Why do medical isotopes just have to *get there*?

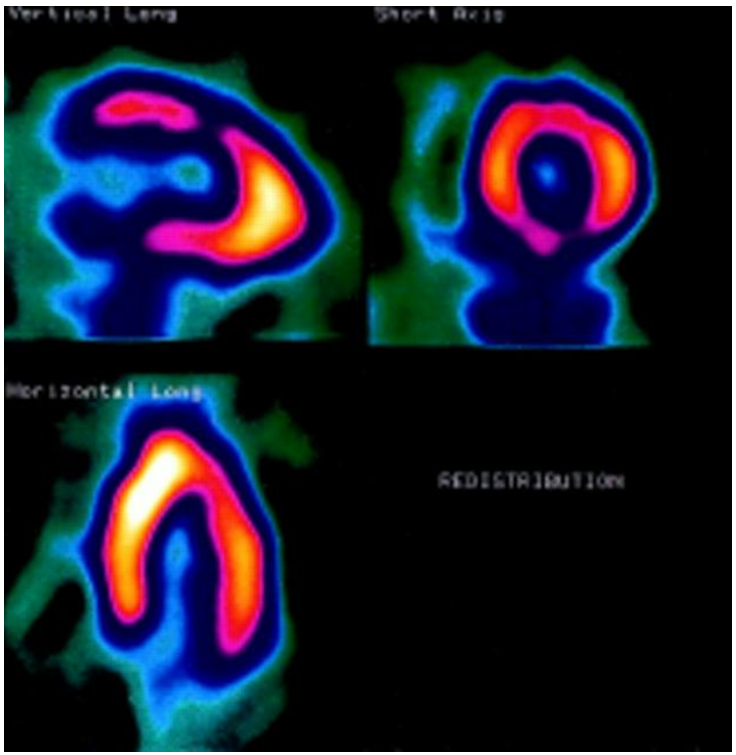
Nuclear medicine

- Medical isotopes are depended upon to diagnose and treat disease
- After administering to patient, the uptake of radioactive atoms in different parts of the body, and the energy this emits, are measured – revealing physiological or biochemical function. Also used to deliver radiation to treat cancer
- 20 million nuclear medicine procedures/year

Importance of medical isotope shipments

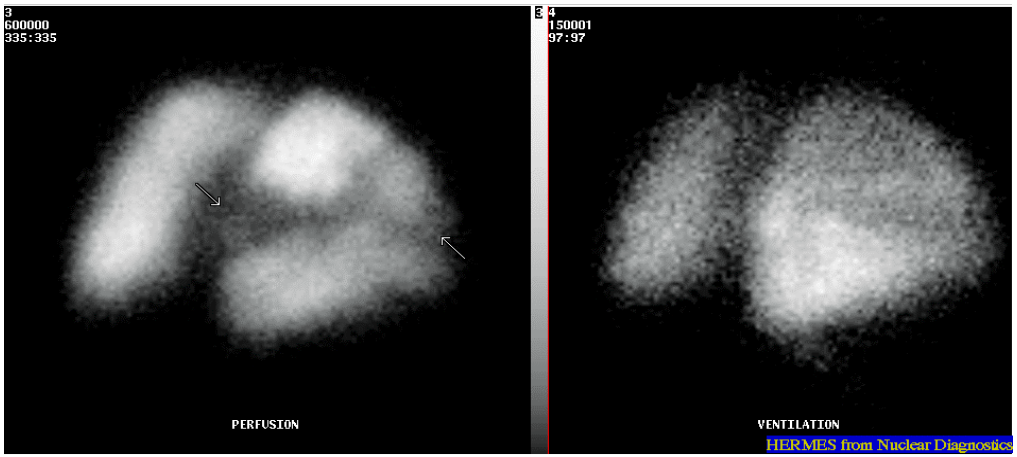
- Serial bone scans show the rapid spread of cancer to the bones before it gives symptoms or shows on an X-ray
  - Patients awaiting surgery, chemotherapy or radiation treatment require accurate staging of their disease.

Importance of medical isotope shipments



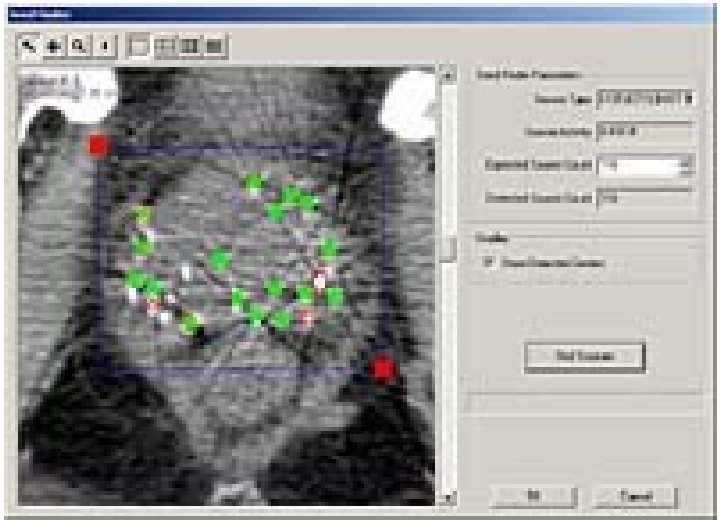
- Determining the heart's condition (and severity of heart disease)
  - Angiograms are riskier and invasive procedures (requires a catheter) vs. a nuclear medicine test
  - Heart disease is the leading cause of death in many countries
  - Used in emergency medicine

Importance of medical isotope shipments

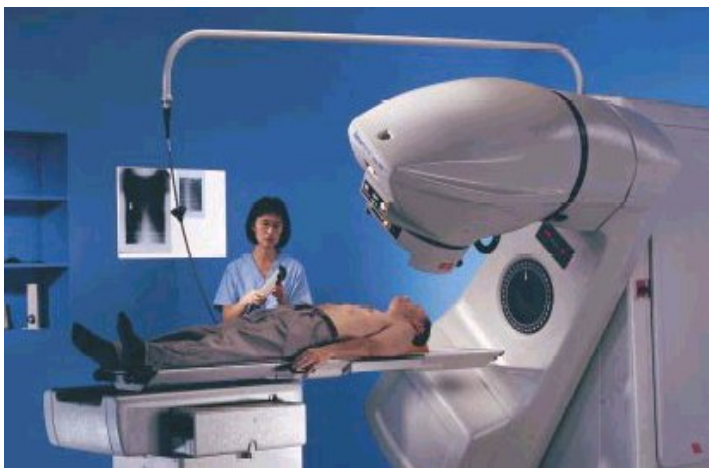


- Scanning the lungs for blood clots
  - Lung scans are critical to post-operative care; following surgery one of the body's reactions is to develop blood clots; diagnosis is critical and urgent care required

Importance of medical isotope shipments

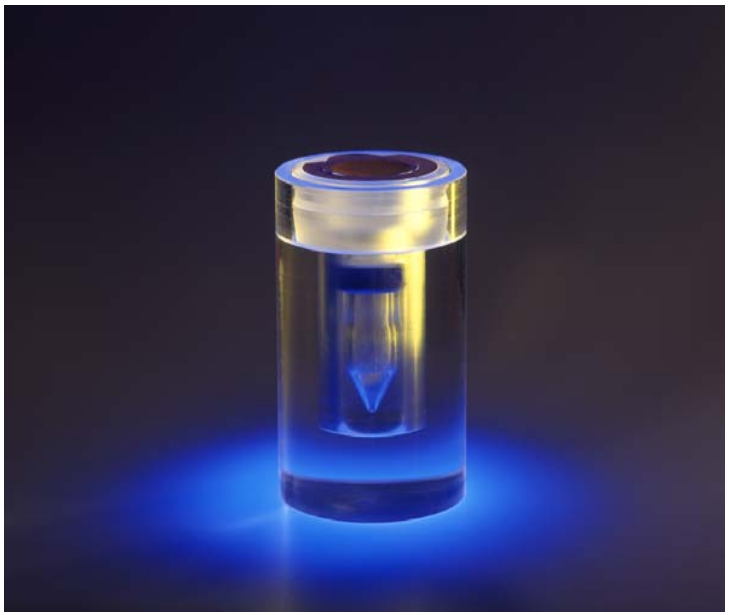


- Treating cancer by inserting radioactive “seeds” into the tumour, such as for prostate and cervical cancer
  - Used in about one-third of prostate treatments



- Treating cancer by directing an external beam of radiation on tumour
  - External beam therapy delivers 45,000 cancer treatments daily in over 50 countries

Importance of medical isotope shipments



- New cancer therapies are being developed
- Radiation is delivered to the tumour at the cellular level - minimizing impact on healthy cells, reducing side effects, improving care, such as for:
  - Liver cancer
  - Brain cancer
  - Non-Hodgkin’s lymphoma

Nuclear medicine applications

- **Molybdenum-99** (technetium-99m): diagnosing heart conditions; bone, brain disorders
- **Iodine-131:** diagnosis/treats thyroid cancer and hyperthyroidism; also used to treat non-Hodgkin's lymphoma, infant neuroblastoma
- **Iodine 125:** treats prostate cancer
- **Iodine-123:** detecting thyroid, brain disorders, heart function
- **Gallium-67:** studying tumours, abscesses, Hodgkin's disease and infections
- **Indium-111:** detecting very small tumours
- **Palladium-103:** treating early stage prostate cancer
- **Thallium-201:** detecting clogged arteries
- **Xenon-133:** pulmonary embolisms; lung function
- **Yttrium-90:** cancer treatment

Shipping medical isotopes

Shipment by Air is essential

- Short half-lives means highly perishable and cannot be held up
  - Same day / next day medical procedures
- Limited number of medical isotope suppliers
- Most countries are importers of such materials
- Air transport is critical

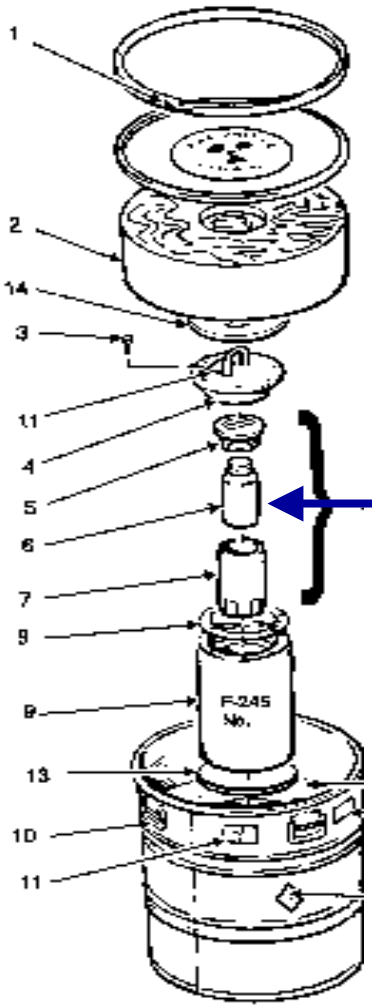
Perishable products: Half-lives

- Technetium-99m: 6.0 hours
- Iodine-123: 13.2 hours
- Yttrium-90: 64.1 hours
- Thallium-201: 3.0 days

Packages

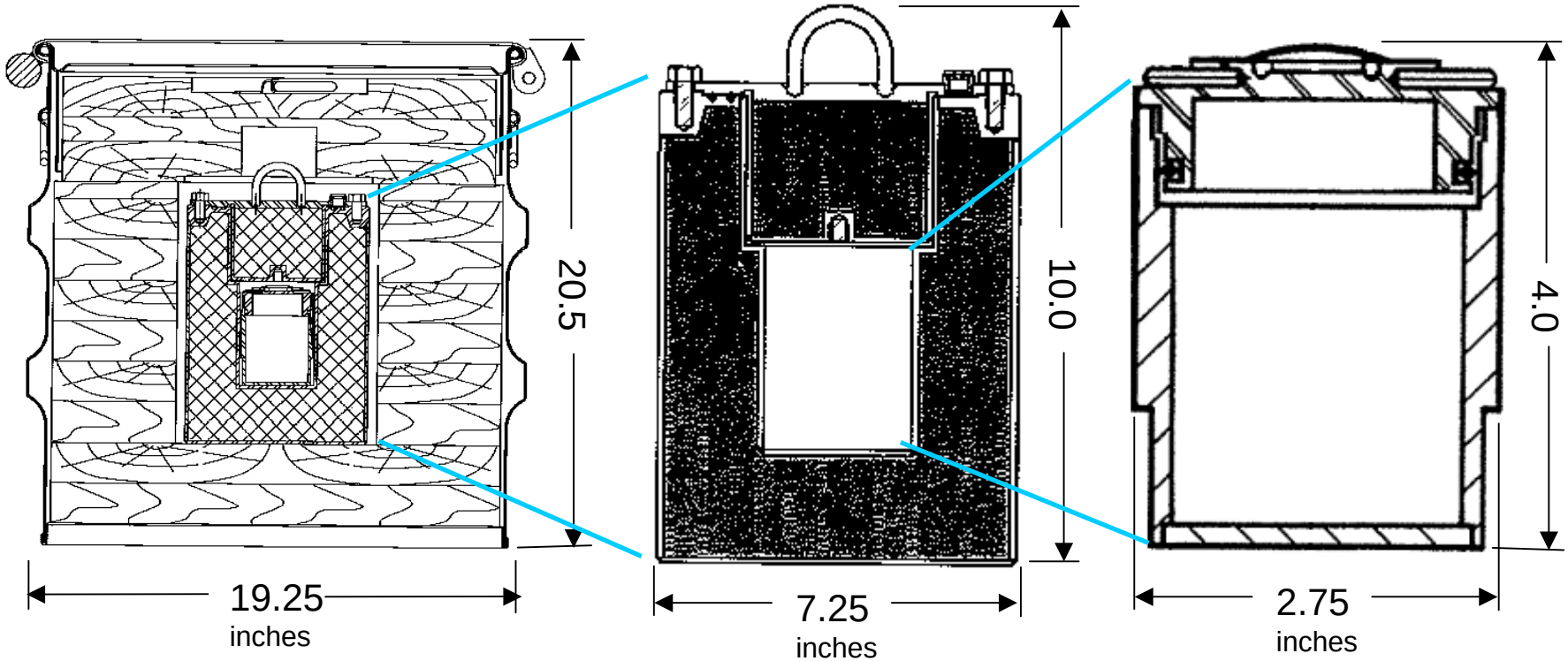
- Shipping molybdenum-99, used ultimately in nearly 80% of nuclear medicine or diagnostic scans
- Type B(U) containers weighing over 150 kg

“What’s inside the container?”



Vial containing
the medical isotope
(~150 ml) of solution

Layers of protection (for Type B(U) Package)

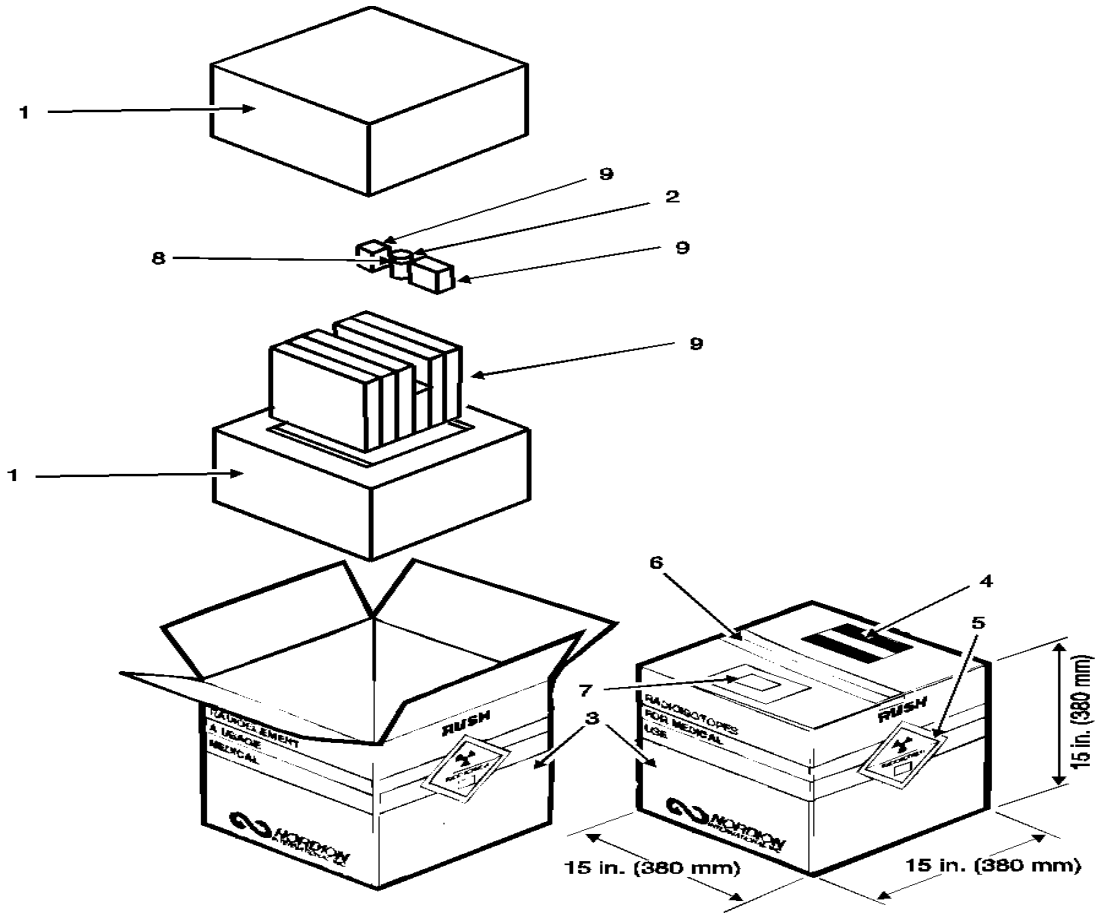


- **Steel over-pack with wooden inserts (for impact and thermal protection)**
- **Lead or depleted uranium vessel (for shielding)**
- **Stainless steel insert (for containment)**
- **Vial containing the medical isotope placed inside this insert**

Packages

- Type A packages for shipping smaller amounts of medical isotopes, such as individual formulations

Layers of protection (for Type A Package)



- Cardboard box
- Styrofoam for impact and penetration protection
- Lead pot for shielding
- Vial

Safety is in the package

"Over several decades of transport, there has never been an in-transit accident with serious human health, economic or environmental consequences attributable to the radioactive nature of the goods."

- IAEA International Conference on the Safety of Transport of Radioactive Material, 2003

Enhancing security

- Safety and security is important to MDS Nordion
- Radioisotopes are manufactured and transported according to stringent standards and new security requirements have been put into place
- As the leading global medical isotope supplier, MDS Nordion pursues global solutions. It is working closely with suppliers, customers and regulators to ensure that its isotope-handling processes remain among the safest and most secure in the industry
- We seek practical and effective requirements for safety and security

“Denials of shipments”

- Globally, specific airlines have stopped transporting radioactive material altogether

“Denials of shipments”

- Airlines that don’t ship on certain routes:
  - A Canadian carrier will not ship to one country due to additional cost of meeting regulatory requirements to handle Class 7 goods
- Airline policy vs. practice:
  - Without explicitly banning the carrying of Class 7, airline policies can effectively prevent shipments
    - One US airline does not allow the total sum of transport indices (TI) to exceed 6 on a passenger aircraft even though the regulations allow for a total TI of 50.
- Pilot refusals:
  - Short-lived perishable medical isotopes are bumped from aircraft
    - Airlines occasionally remove medical isotopes from flights because animals were loaded on the aircraft – this can postpone shipments to the next day and undermining usefulness

Summary of denials

- The denials of shipment are not attributable to a single problem or item but rather a combination of many factors:
  - Regulatory-compliance
  - Airline administrative requirements
  - Pilot acceptance / Other cargo takes priority (eg, animals)
  - Cargo handling practices
  - Training burden
  - Economic considerations
  - Concerns with handling class 7 materials

Implications of denials

- The number of carriers carrying Class 7 is declining
- The risk is growing that “last remaining carrier” on a route denies
- The risk is growing if key hubs in key countries deny
- Increasing costs and delays in getting isotopes to customers… or, no delivery option

Ensuring shipments

- The world depends on beneficial uses of nuclear technology to diagnose and treat disease

Moving forward

- Engage a process to:
  - Support international efforts now underway to address the matter
    - IAEA-lead process
  - Work together to better understand the issue
    - Partner with related organizations
  - Identify ways to facilitate shipments
    - Communication, education
    - Training
    - Identify regulatory issues