Proceedings of the 17th International Symposium on the
Packaging and Transportation of Radioactive Materials
PATRAM 2013
August 18-23, 2013, San Francisco, CA, USA

Safe, Efficient and Reliable Transport of Nuclear Medicine Sources in India

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ABSTRACT

Large number of applications of radioactive material in medicine, industry, agriculture and research necessitates its transport from one place to another. In view of the radiation hazard associated with the transport of radioactive material, these are required to be transported in accordance with the national regulations. In India, Atomic Energy Regulatory Board (AERB), the Competent Authority, enforce the regulations for the safe transport of radioactive material through a Code. The code is based on the IAEA regulations for "Safe Transport of Radioactive Material" with modifications to suit the conditions of transport specific to India. In India, a considerable supply of the radioisotopes, particularly short-lived, used in nuclear medicine, is of foreign origin and the quantum of such imports is increasing annually. In this paper, the current administrative procedures and controls followed for safe transport, use and disposal of radioactive material used in nuclear medicine in India are discussed in detail.

INTRODUCTION

With the rapid increase in the use of radioactive material (RAM) in different fields, the quantum of transport of RAM from one place to another is also increasing. Even though there is a potential for radiation hazard in the transport of RAM, such hazard is controlled to an acceptable level by following the regulations for safe transport of radioactive material [1]. The "Regulations for Safe Transport of Radioactive Material" of the International Atomic Energy Agency (IAEA) is the backbone of the regulations in many countries. These regulations aim at providing an acceptable level of control of the radiation hazards to persons, property and the environment that are associated with the transport of radioactive material. In India, safety in transport of RAM is governed by AERB, the Competent Authority. Safety is ensured by implementing the provisions of the AERB Safety Code and Guides [2], which are based on the IAEA regulations [3] with amendments to suit the Indian ambient conditions of transport.

Different modes of transport

The RAM needs to be transported from manufacturer to user, from one user to another, and from user to disposal site, including loading, unloading and storage-in-transit. These types of transport are performed by air transport, road transport and rail transport. It can be noted that no particular mode of transport is considered preferable to others. The consignor taking into consideration convenience as well as cost of transport involved can choose any mode of transport. However, for nuclear medicine sources air is the preferred mode of transport since it can transport in the shortest possible time, which is very much essential for short-lived sources used in nuclear medicine.

Procedure for transport of RAM by air

- Import, export and domestic transport of short-lived RAM involve air transport.
- Any carriage of RAM by air through, into, or over India requires prior permission from the Director General of Civil Aviation (DGCA), New Delhi.
- For any indigenous procurement or import of RAM, the user needs to obtain No Objection Certificate (NOC) from AERB.
- The NOC for import/export is also meant to facilitate the necessary clearance from Customs.
- With the copy of the NOC issued by AERB, the user has to approach DGCA with the details of consignment (like, type of package, Transport Index, category, the proposed nature of application of the RAM), name of consignor, name of consignee, ports of embarkation/disembarkation in the format prescribed by the DGCA.
- DGCA issues the permission for air freighting to the applicant only on the basis of the No Objection Certificate (NOC) for import/export/movement in the country issued by AERB.

Procedure for transport of RAM by road

Generally, nuclear medicine sources being short-lived, are transported by air. Many work places are not connected directly by air. Therefore, the RAM needs to be transported by road from the nearest airport to the work place. For the safety of RAM during road transport the following procedure is followed.

- The user is required to comply with the transport regulations during transport of RAM from the nearest airport to work place.
- For those shipments, which fall short of regulatory requirements and are qualified for transport under Special Arrangement with additional compensatory safety measures; require prior approval from the Competent Authority, i.e. Chairman, AERB.

- After ensuring that it is safe for transport, the consignor is required to include transport documents such as Consignor's Declaration (a declaration by the consignor about the proper classification, packing, marking and labelling of the consignment in accordance with the applicable regulations for transport of radioactive material), TREMCARD (Transport Emergency Card, which gives instructions regarding emergency management procedures, relevant address, telephone no. Fax no. for quick communication), Instructions to the Carrier(which are DO's and DON'Ts for the carrier engaged for carriage of RAM), Instructions in Writing (which gives information about the different types of packaging deployed, procedures for emergency handling and particulars regarding set of protective devices to be carried).

Procedure for transport of RAM by rail

With effect from 15.7.2001, Indian Railways has started accepting RAM for transport by rail by including provisions of RAM in chapter VII of their Red Tariff No. 20. With the necessary clearance from AERB, any user can book the radioactive consignment containing those RAM (71 radioactive items) listed by Indian Railways in their Red Tariff at notified stations by declaring it as dangerous goods, following rigorously their prescribed procedure during booking, loading/unloading, transit and delivery of the consignment, and forward it to notified stations as destinations.

Use of radioisotopes in nuclear medicine

In India, there are 179 approved nuclear medicine centres, which use radiopharmaceuticals for diagnostic well as therapeutic applications and palliative treatments. The regulatory approvals of such centres include plans of laboratory and treatment room, commissioning of equipments and facilities. The regulations [4] require that the applicant shall obtain approval of the competent authority for introducing any new radio pharmaceuticals into use for diagnostic as well therapeutic applications and the appointment of a trained, qualified and approved nuclear medicine physician(s) and technologist(s). Further, it is an mandatory requirement to have a Radiation Safety Officer (RSO) in any nuclear medicine facility carrying out in-vivo/in-vitro diagnostic investigations (other than Radio Immune Assay) and radio-nuclide therapy in India.

A sizable supply of the radioisotopes used in nuclear medicine centres in India is imported. Table I & II give the radioisotopes, range of activity, and approximate no. of shipments per year for imported and domestic supply respectively. ^{153}Sm has been recently inducted into use for palliative treatments after the clinical trials have been approved by AERB.

Table I: Shipments of radioisotopes imported to India for Nuclear Medicine use

Radioisotopes	Range of Activity (MBq)	No. of Shipments per Year
^{133}Ba	3.7-9.25	10
^{51}Cr	18.5-18500	210
^{169}Er	74-1110	250
^{57}Co	18.5-740	60
^{59}Fe	37-185	50
^{67}Ga	74-5550	2650
^{111}In	37-3700	1200
^{123}I	148-1110	50
^{131}I	7.4-18500	3000
^{99}Mo	444-29900	3200
^{32}P	370-14800	320
^{186}Re	185-1850	290
^{75}Se	370	60
^{89}Sr	37-1850	215
^{99m}Tc	7400-37000	120
^{201}Tl	37-19980	3500
^{133}Xe	444-3700	500
^{90}Y	185-3700	620

Table II: Shipments of radioisotopes of domestic supply for nuclear medicine use.

Radioisotopes	Range of Activity (MBq)	No. of Shipments per Year
^{13}1I	1.85-22200	2610
^{99}Mo	3700-11100	3700
^{32}P	370	1000
^{153}Sm	1850-7400	45

Safe disposal of nuclear medicine sources

In India, the safe disposal of any radioactive waste is governed by Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, issued under Atomic Energy Act, 1962(33 of 1962). These rules for the safe disposal of disused sources are enforced by AERB. As per the definitions under these rules, 'disposal' means release of any material to the environment in a manner leading to loss of control over the future disposition of the radionuclide's contained therein and includes emplacement of waste material in a repository; 'radioactive waste' means any waste material containing radionuclide's in quantities or concentrations as prescribed by the Competent Authority by notification in the Official Gazette. Any radioactive waste generator in India needs to be authorized by Chairman, AERB for its disposal. The authorized waste generator has to ensure that the waste materials are disposed of in accordance with the provisions of the rules, and in accordance with the terms and conditions laid down in the authorization issued by the Competent Authority. Records of waste disposal are to be maintained and periodic status reports are to be submitted to the Competent Authority by the authorized waste generator. The Competent Authority may cancel an authorization issued under the rules or suspend it for such period as it thinks fit, if in its opinion, the authorized person has failed to comply with any of the conditions of the authorization or with any provisions of the Act or the rules after giving the authorized person an opportunity to show cause and after recording reasons.

Except few sealed long lived sources, which are used for quality assurance programme, most of the unsealed radioisotopes used in nuclear medicine centres in India are disposed off locally. The radioactive wastes are discharged into a sanitary sewerage system or disposed off by burial into soak pits prepared in an exclusive burial ground approved by AERB; and ensured by all the authorized waste generators that disposals are within the limits prescribed by the Competent Authority.

CONCLUSION:

The trend by which nuclear medicine centres are coming up in the country (65 in 1980, 101 in 1990, 141 in1999 and 179 in 2002) suggests that it is bound to increase the quantum of transport of sources for use in nuclear medicine. At the same time, the safety of transport, application and disposal of the sources can not be compromised with their heavy demand, urgent requirements and huge waste management by passing all the requisite controls and administrative procedures. In order to ensure safety in every stage of transport, application and disposal of the sources both the requisite technical as well administrative procedures are to be strictly followed. A well-balanced regime of technical and administrative controls ensures the maximum benefit with minimum hazard to humankind by the use of radioisotopes.

REFERENCE

1) INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, Safety Standard Series No.ST-1, IAEA, Vienna (1996).
2) ATOMIC ENERGY REGULATORY BOARD, Safety Code for Transport of Radioactive Material Safety Code, SC/TR-1, 1986, AERB, Mumbai (1986).
3) INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material,1985 Edition(As Amended 1990), Safety Series No.6 ,IAEA, Vienna(1990).
4) ATOMIC ENERGY REGULATORY BOARD, Safety Code for Nuclear Medicine Facilities, SC/MED-4(Rev.1), 2001, AERB, Mumbai (2001).