Radiopharmaceuticals Transportation by Highway and Air—Operations and Regulatory Control

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INTRODUCTION

The transportation conditions for radiopharmaceuticals are different than most other radioactive materials. The characteristics of the radioactive products and the needs of the shippers and consignees have resulted in the evolution of special carriers and delivery systems. Many of the resulting worker activities probably were not anticipated several decades ago when the basic radiation safety assumptions were established for the transportation regulations. The basic concept of limiting only the dose rates to workers and not the accumulated doses may no longer be valid for transportation of radiopharmaceuticals.

The advancements in nuclear medicine and increased uses of radiopharmaceuticals has resulted in some transportation workers receiving occupational radiation doses that clearly classify them as "radiation workers" according to international and national standards for radiation protection (IAEA 1982 and USEPA 1987). The fundamental radiation protection provisions of our transportation safety regulations were established before many of today's nuclear medicine protocols existed and when the "nuclear medicine departments" were not present in most hospitals. The transportation of radiopharmaceuticals with short half lives is the primary cause for the greater doses received by these transport workers. Frequent and repeated shipments to the same medical facility generate delivery patterns with repeated package handling by the same workers.

Dr. William H. Briner of the Duke University Medical Center, Durham, North Carolina, recently told me that at this time about 33% of all patients entering hospitals for treatment are involved with a nuclear medicine protocol (Briner 1989). This represents about 8 million in-vivo and 100 million in-vitro procedures per year.

TRANSPORTATION SYSTEMS

The expedited delivery networks that supply and maintain the variety of short half life radiopharmaceuticals needed by the medical facilities involve extensive coordination between radiopharmaceutical manufacturers/shippers and the carriers/deliverers in the air and highway transportation industry. These networks with special capabilities regularly make "24 hour" deliveries 3000 miles across the country, involving 4 or 5 carriers. The deliveries are as routine as getting the Sunday newspaper at the door at 5:45 AM. The network also provides "overnight delivery" when unique or special radiopharmaceuticals are needed. The radiopharmaceutical shippers and the air and highway carriers know the system and how to expedite the routine and special shipments. Shipments are mostly prepaid.

A hypothetical shipment operation could start with 150 packages going from a supplier by truck to a nearby airport. Half of the packages could go by plane to an airport 600 miles away where some packages could be loaded onto another plane with radiopharmaceutical packages from another supplier. The second plane could go to another airport 1500 miles away. At that airport 4 or 5 trucks could take portions of the load and depart along different routes. At predesignated locations and times other vehicles would be met to take some of the packages for delivery to medical facilities close to or perhaps 200 miles away from the point of pickup.

Another hypothetical shipment could start with several hundred radiopharmaceutical packages in a tractor trailer van beginning a 1000 mile run along an interstate. At specified times and locations enroute, groups of packages could be off-loaded to other trucks that would travel side routes making deliveries to medical facilities and/or delivering packages to smaller vehicles that would make end-point deliveries to the medical facilities off of the side route. The tractor-trailer on its 1000 mile run might also pick up packages from a truck that had received packages from a second supplier. The combined load of packages could go on to the end of the 1000 mile run or to intermediate points for distribution.

REGULATORY CONDITIONS

International and national regulations for the safe transportation of radioactive materials focus primarily on packaging of the materials and assuring package performance during normal and accident conditions of transportation (IAEA 1979 and Hazardous Materials Regulations 1988). As a result of the standards, the radiation doses to transport workers, emergency response personnel, and the public, from packaging failures, have been exceptionally low when accidents occur. None of the other hazardous or dangerous goods under the regulations of the United Nations and national authorities can boast the near-perfect safety record of insignificant injuries and no deaths resulting from releases of the material during transportation accidents. Apparently the containment, shielding, heat dissipation, and criticality control (when appropriate) have been adequate for the packaging of radioactive material shipments that have been involved in normal and accident conditions. For that excellent performance, the regulated community and regulators deserve credit.

The 1985 International Atomic Energy Agency (IAEA) regulations (IAEA 1986) specify the need for controlling the radiation doses received by transportation workers and members of the general public. There are some general statements that regulations should be developed by the transportation regulating authority that will require establishing radiation protection controls that will depend on the different levels of annual doses that may be received by the transportation workers. The 1973 and 1985 IAEA regulations and the present U.S. Department of Transportation regulations do not have provisions or control mechanisms for monitoring or controlling carrier activities to limit radiation doses to workers. There are provisions that limit radiation dose rates, but there are no provisions for limiting the duration of exposures. Only the protection of undeveloped film has provisions for a total dose. For film there are time factors associated with dose rates, but there are no time factors listed for personnel.

Dose rates to persons are controlled in the regulations by the limits on 1) The radiation level at package surfaces, 2) Transport Index (TI) of packages, 3) radiation levels of exclusive use conveyances, 4) separation distances between personnel from groups of packages, and 5) total TI of packages in a group.

Some of the factors not restricted by transport regulations which influence the magnitude of the radiation dose received by workers include the following:

- Time and distance of workers near packages during loading and unloading operations,
- Frequency or repetition of operations,
- Time the worker is exposed to allowed radiation levels while in transit,
- Total of the TI of all packages handled at a facility or by a given conveyance or worker during a specified time period, and
- Training of workers in the use of practices, procedures, and equipment that will minimize dose.

The transportation of radiopharmaceuticals involves large numbers of packages, repetitious transport and delivery patterns and contact handling by the workers. Hence, it is not surprising that these workers receive radiation doses greater than workers transporting other radioactive materials.

Studies reported through the IAEA, and the paper by James Shuler in this session of PATRAM 89, indicate transport workers receive very low radiation doses during highway transportation of spent nuclear fuel, other large Type B packages, and low level radioactive waste (Shuler 1989). In each of these three cases, the transport worker typically is not involved during loading, securing, or off-loading of the radioactive material packages; the total number of these operations in this country during a year are low compared to radiopharmaceutical shipments. Mr. Shuler's report shows that the highway transport workers receive significant doses from radiopharmaceutical packages.

CONTROL OF SPECIAL CARRIERS

Regulatory control of the radiation doses to many of the highway and air workers transporting radiopharmaceuticals in the United States is accomplished by two exemptions from the Department of Transportation (DOT) regulations. (An exemption from DOT regulations, is similar in concept to a Competent Authority-issued Special Arrangement Certificate under international (IAEA) regulations.) These two DOT exemptions, E-7060 for air and E-8308 for highway, allow specifically authorized carriers to transport in a conveyance greater numbers of non-fissile radioactive materials packages (over 50 TI total) than normally allowed by the DOT regulations. Additionally, the restrictions on the minimum separation distances between packages and spaces occupied by operators are waived. The carriers gain operational and financial efficiency when given relief from total TI and separation distance requirements.

A significant requirement of both exemptions is a formal radiation protection program supervised by a professional radiological specialist; this program includes regulatory and radiological safety training for the workers. Of special significance, the workers must wear radiation dosimetry devices to measure radiation doses received while handling and transporting packages.

Exemption E-7060 was first issued in 1976, and at the present time, three air carriers are authorized to operate under the exemption. Since 1976, 15 other air carriers held status under the exemptions, but subsequently withdrew or were dropped by DOT. The first issuance of E-8308 was in 1980. At the present time 7 highway carriers hold status, and 4 others have withdrawn or have been dropped.

It is notable that under both exemptions there are carriers who have extensive fleets and others have only a few units. The same basic radiation safety and operational requirements apply to both small and large operators, but the size of the exemption operations probably influences some costs, such as the amount of time required by the health physics consultants who supervise the radiation safety programs.

The requirements of the two exemptions are briefly described by the outline below:

Requirements for both E-7060 and E-8308

A. Radiation protection program.

1. Wearing radiation dosimetry devices.
2. Qualified health physicist to supervise radiation protection program.
3. Program per OSHA standard (29 CFR 1910.96).
4. Radiation exposure to be kept as low as reasonably achievable (ALARA).
5. Training of workers about regulations and radiological safety is required by exemption, by 49 CFR and by 29 CFR.
6. Dose limit is 1250 millirems per quarter, not 5000 millirems per year.
7. Carrier personnel should be aware of their current and cumulative radiation doses.

B. The radiation levels outside conveyances are limited and must be measured and recorded after loading and before departure.

C. Aircraft and vehicles must be monitored for contamination after any abnormal occurrence and after use for transport of Radioactive Materials, and before being used for transport of cargo other than Radioactive Materials.

D. Radioactive Material packages must not be interlined to carriers not party to E-8308 or E-7060, if the total TI per vehicle will exceed 50.

E. Documents carried with usual shipping documents include: copy of exemptions, report of radiation survey, descriptions of radioactive materials, and emergency response procedures for operators and emergency service personnel.

F. Quarterly reports to DOT must indicate; radiation doses received by workers, radiation safety improvement activities, radiations level measurements of conveyances, and a description of abnormal occurrences and approximate total TI transported during the quarter.

G. Accidents and lost packages must be reported promptly to DOT.

H. Fissile radioactive materials cannot be transported and radiation sensitive materials such as photographic film can be carried only if procedures are approved by DOT.

I. Operating procedures shall limit and avoid unnecessary radiation exposure to the public and to workers not under the radiation protection program.

Additional Special Requirements for E-7060

A. Airport management and the Federal Aviation Administration (FAA) of DOT must be advised of operations and locations where over 50 TI of packages are loaded onto aircraft.

B. FAA must be informed of all flights carrying over 50 TI or carrying personnel other than flight crew.

IMPACT

Applicants for exemptions from DOT regulations must show that the exemption operations will achieve equal or greater safety than if the operations were conducted within the regulations. DOT believes that the delivery of large numbers of radioactive material packages under these exemptions results in lower total worker doses than if the shipments were all made with a greater number of vehicles each with packages totaling less than 50 TI. Without the exemption a greater number of vehicles would be needed, and the operators would not need to be under a formal radiation protection program with dosimetry and special training. Equipment and procedures for reducing radiation exposure and package handling can be more effective with greater volumes in transport. Reducing the number of vehicles transporting these materials reduces the probability of an accident occurring with radioactive materials involved.

Another paper by Finley, et. al., of Sandia National Laboratories given in another session of this PATRAM 89 analyzes the risks of surface and air accidents with large numbers of Type A packages, such as radiopharmaceuticals (Finley, et. al. 1989). That analysis, and several highway accidents that have occurred in the United States, show that radiological consequences of accidents with large numbers of Type A packages are not significant.

The radiation dose records received by DOT for the personnel handling and transporting radiopharmaceuticals packages under E-7060 and E-8308 clearly indicate the need for and value of radiation protection programs and worker training. Even with total TI of packages increasing, the average quarterly dose per worker had not shown much change. Without surprise, it is observed that persons receive greater doses from handling packages (loading and unloading) than they receive in

transit. Dosimetry data from the highway and air exemption holders indicate air carrier workers generally get lower doses than highway carrier workers. DOT does not have much data on dose per TI received by workers doing different functions, but a preliminary study in 1981 by the U.S. Nuclear Regulatory Commission showed that the total TI of packages passing through a facility might be an indicator of the maximum doses expected to be received by the workers (Smith, et. al. 1982).

Regulations for limiting radiation doses of transportation workers need to be developed. First steps might involve identifying operating conditions and activities that correlate to radiation doses received. After the conditions and activities are identified, regulatory provisions that monitor and control the radiation doses must be formulated. Regulatory changes being developed by the Department of Transportation to achieve consistency with the present IAEA regulations considers the need to limit doses to workers. However, the current expected changes will not define the methods for controlling some of the carrier functions discussed in this paper. A difficult problem to be resolved in the future will be scaling the regulatory controls to adequately protect workers receiving significant doses, and still allow carriers occasionally to transport a few packages without unnecessary burdens.

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