

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

November 7, 1989

NRC INFORMATION NOTICE NO. 89-74: CLARIFICATION OF TRANSPORTATION REQUIREMENTS
APPLICABLE TO RETURN OF SPENT RADIOPHARMACY
DOSAGES FROM USERS TO SUPPLIERS

Addressees:

All manufacturers and distributors of radiopharmaceuticals for medical use, nuclear pharmacies, and medical licensees.

Purpose:

This notice is provided to answer questions that frequently have arisen about the regulatory requirements applicable to transportation of packages, containing radioactive materials in the form of "spent" radiopharmacy dosages, from the user back to the original supplier. Most of these questions have involved the performance of "shipper" responsibilities in such shipments.

It is expected that addressees will review the information here for applicability to their licensed activities, and consider actions, as appropriate, to avoid problems in transport of such materials. However, suggestions contained in this notice do not constitute any new U.S. Nuclear Regulatory Commission (NRC) requirements, and no written response is required.

Background:

In the practice of nuclear medicine in the United States, many thousands of routine shipments of diagnostic radiopharmaceuticals are made each day. Most of these shipments are from the "supplier" radiopharmacy, using private vehicles, to the licensee "user," e.g., a hospital or physician. One major supplier, in fact, transports between 1000 to 3000 shipments daily. As a part of the process, the user-licensee then returns such packages to the supplier, now containing residual "spent" dosages, contaminated syringes, syringe shields, and multi-dose vials. The user places these materials in the original as-received packagings, which are then picked up routinely by the supplier at the time "fresh" packages are delivered to the users.

Discussion:

Pursuant to 10 CFR Section 71.5, NRC licensees who either transport licensed radioactive material outside of their place of use, or deliver such material to a carrier for transport, must comply with the applicable requirements of the U.S. Department of Transportation (DOT) regulations 49 CFR Parts 170 to 179.

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Radiopharmacy material shipments almost always involve situations where the supplier is a "shipper" acting as a private carrier. The hospital or physician "user" most often is transferring the residual spent-dosage packages to the supplier, who then also assumes responsibility for performing the "shipper" functions, as well as the carrier functions.

The questions/answers that follow are intended to clarify the most frequently asked questions which have arisen:

Q1. Who must act as the "shipper?"

A. Either party, e.g., the radiopharmacy (supplier) or its customer (user) may act as the shipper. DOT regulations provide no specific definition of a "shipper." The regulations do prescribe many requirements applicable to shippers, consignors, or the "...person who offers for transport." DOT has taken the position that shipper functions actually may be performed by more than one party. This is, of course, the situation in the case of radwaste "brokers." In that case, the waste generator may perform certain of the shipper functions, such as filling, closing, and marking the packages and preparing a shipping paper. The generator then transfers the shipment to the broker, who receives and takes title to the packages, prepares a new manifest, and loads the package onto his vehicle for transport to a collection point or to a burial site. The broker, in effect, becomes the shipper acting as a private carrier. Likewise, in radiopharmacy shipment operations, the supplier functions as a shipper acting as a private carrier, in both the delivery of fresh packages to the user, as well as in the pickup of the spent-dosage packages from the user. In any case, all parties acting as shippers assume liability for any violations that may occur.

Q2. In the case of radiopharmacy spent-dosage shipments from the user back to the supplier, who is it preferable to have act as the shipper?

A. As stated previously, either party may act as the shipper, but it is usually preferable that the supplier assume the responsibility. That is because the supplier is generally more knowledgeable than the user about regulatory requirements for shippers and, likewise, is more apt than the user to be adequately equipped to meet those requirements. NRC strongly recommends that the supplier and the user sign an agreement clearly delineating the respective roles and responsibilities of each party, as they relate to shipper functions, thus eliminating any potential misunderstandings. With such a written agreement, the supplier may rely on the user to act as his agent in carrying out certain shipper functions. In such a case, NRC will hold that supplier totally responsible for ensuring that all shipper requirements are met. The agreement should be maintained on file and furnished to an inspector upon request. In the absence of such a written agreement, NRC will generally consider the end-user licensee to be solely responsible for compliance with regulatory shipper requirements when returning radiopharmacy packages to the supplier. This is because the end-user in this case is the point of origin of the shipment.

- Q3. What quality control measures would be appropriate on the part of the supplier?
- A. The return of spent radiopharmacy dosages as limited-quantity packages is not technically subject to the formal shipper requirements for a quality control program, as outlined in 49 CFR Section 173.475, as would be for instance, the shipping of labeled Type A packages. However, if the supplier relies on the user to perform certain shipper functions on his behalf, it is appropriate that the supplier establish procedures to ensure compliance with shipping requirements for limited-quantity packages. Such a program should include: establishment and dissemination of packaging procedures for the users to follow; provision for training of the involved user personnel; periodic audits by the supplier of the user's performance, to identify discrepancies; and provisions to effect corrective actions by the user when discrepancies are observed. The specifics of this quality control program should be covered in the written agreement between supplier and end user. (See Question 2.)
- Q4. Limited-quantity packages of return shipments of spent dosages sometimes are placed within opaque plastic bags which may be either five-sided slipcovers or six-sided covers, providing almost total enclosure of the shipment. This procedure often is used in lieu of performing contamination surveys to assure compliance with 49 CFR Subsections 173.421(c) and 173.443(a). Please comment on this?
- A. Yes. In the first place, the two types of bags in question do not afford the same quality of protection. The slipcover bags, since they do not totally enclose the packaging, are not as effective as the six-sided covers in preventing contamination. Although either of the bags may be a means of avoiding surface contamination, this is not the intended use. The primary purpose of both types of bags is to display the limited-quantity statement required by 49 CFR Subsection 173.421-1 and to cover the labels and marking that were appropriate when the package first came into the user's facility. In order to ensure compliance with the limits for surface contamination, as stated in Subsection 173.421(c), and certified to by the statement on the bag, NRC strongly recommends that a contamination survey be performed, although this is not mandatory for limited-quantity packages. If contamination levels are found to exceed the regulatory limits of Subsection 173.443(a), the user or the supplier (if that supplier has assumed responsibility for the shipper functions) will be found to be in violation of the section, regardless of whether a contamination survey was made.
- Q5. Some radiopharmaceuticals are returned to a supplier unused by the end user and not "spent." These packages will usually be Type A, since they exceed the activity limits for a "limited quantity," as specified in 49 CFR Sections 173.421 to 173.423. Does this present any complications?

- A. Definitely. Different regulatory requirements are specified for packaging, labeling, marking, and shipping papers for Type A packages. If the end user fails to inform the supplier that such packages are not limited-quantity, the packagings, labels, markings, and shipping papers may not be appropriate to the material being returned. Whatever arrangements have been established in the written agreement between the two parties, as to who performs the specified shipper functions, should also hold for these situations. The more formal requirements for a quality control program, as outlined in 49 CFR Section 173.475, would now apply for a package that contains more than a limited quantity, e.g., a Type A package.
- Q6. Packages containing residual materials and spent dosages usually contain much less radioactivity than the original, incoming Type A, labeled packages. What are the principal requirements applicable to such limited quantities in order that they might qualify as "Radioactive Material, limited quantity" packages?
- A. The requirements of 49 CFR Section 173.421, Subsection 173.421-1, and Section 173.423 apply.
Briefly, these requirements state that:
1. The package must be "strong, tight...";
 2. The radiation level at any point on the external surface of the package may not exceed 0.5 mrem/hr;
 3. The radioactive content may not exceed the limits specified in 49 CFR Section 173.423;
 4. Removable radioactive surface contamination on the exterior of the package may not exceed the prescribed limits, e.g., 2,200 d/m/100 cm² [49 CFR Subsection 173.443(a)];
 5. The outside of the inner packaging, or if there is no inner packaging, the outside of the package itself must be marked "RADIOACTIVE;" and,
 6. A notice, with prescribed wording per 49 CFR Subsection 173.421-1, must be included in, on or identifiably with the package, certifying that the package meets the requirements for limited-quantity radioactive materials.
- Q7. I understand that distribution of nuclear medicine materials in the United States is largely accomplished by a network of non-licensed contract motor and air carriers who operate under exemptions issued by DOT (DOT E-8308 for highway shipments and DOT E-7060 for air shipments). Does this information notice relate to those shipments?

A. No. The contract carriers involved as parties to those two exemptions are license-exempt and therefore subject solely to DOT jurisdiction. In effect, they are responsible for the carrier requirements of DOT regulations, not the shipper requirements. They are also responsible for maintenance of the radiation-protection programs, as specified in each exemption. In cases where "spent" packages of MO⁹⁹ - TC⁹⁹ generators are being returned by an end-user to a supplier using the contract carrier, the end-user is the originator of the return shipment and clearly is responsible for the shipper functions.



Robert F. Burnett, Director
Division of Safeguards and
Transportation
Office of Nuclear Material Safety
and Safeguards

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Attachment: List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
89-73	Potential Overpressurization of Low Pressure Systems	11/1/89	All holders of OLs or CPs for nuclear power reactors.
89-72	Failure of Licensed Senior Operators to Classify Emergency Events Properly	10/24/89	All holders of OLs or CPs for nuclear power reactors.
89-71	Diversion of the Residual Heat Removal Pump Seal Cooling Water Flow During Recirculation Operation Following a Loss-of-Coolant Accident	10/19/89	All holders of OLs or CPs for nuclear power reactors.
89-70	Possible Indications of Misrepresented Vendor Products	10/11/89	All holders of OLs or CPs for nuclear power reactors.
89-69	Loss of Thermal Margin Caused by Channel Box Bow	9/29/89	All holders of OLs or CPs for BWRs.
89-68	Evaluation of Instrument Setpoints During Modifications	9/25/89	All holders of OLs or CPs for nuclear power reactors.
89-67	Loss of Residual Heat Removal Caused by Accumulator Nitrogen Injection	9/13/89	All holders of OLs or CPs for PWRs.
89-66	Qualification Life of Solenoid Valves	9/11/89	All holders of OLs or CPs for nuclear power reactors.
88-46, Supp. 4	Licensee Report of Defective Refurbished Circuit Breakers	9/11/89	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

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Concurrence with minor Editorial changes:
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SGDB *	SGDB *	SGDB *	IMNS *	SGTR *	SGTR
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