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*Department of Transportation Regulations Pertinent to
Nuclear Pharmacy and Nuclear Medicine Practice*

by:

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DEPARTMENT OF TRANSPORTATION REGULATIONS PERTINENT TO NUCLEAR PHARMACY AND NUCLEAR MEDICINE PRACTICE

STATEMENT OF OBJECTIVE

This lesson provides instruction in the Department of Transportation (DOT) regulations for the highway transportation of packages containing radiopharmaceuticals. Federal regulations require persons who offer, transport, or otherwise handle hazardous materials, such as radiopharmaceuticals, to be trained in (1) requirements of the DOT hazardous materials regulations (Awareness Training); (2) applicable requirements specific to the function of the employee, e.g., a nuclear pharmacist (Function Specific Training); and (3) measures to protect the employee from the hazards associated with material. It is the responsibility of the employer to certify compliance with these training requirements.

This lesson assumes that the nuclear pharmacy employee received safety training in radiation protection as a license condition. Upon successful completion of this lesson, the reader should be able to:

1. discuss various aspects of Awareness Training, including:
 - a. the requirements for who must be trained, how often and by whom they must be trained, and what training records must be available to an inspector
 - b. the organization of the DOT hazardous materials regulations
 - c. the relationship between the Nuclear Regulatory Commission (NRC) and the DOT
 - d. a suggested method to find a specific regulation

2. discuss various aspects of Function-Specific Training, including:
 - a. criteria for selection of the proper shipping name of the material being transported
 - b. criteria for selection of authorized packaging
 - c. performance requirements for Type A packaging
 - d. the regulations pertaining to the labeling and marking of packages, the preparation of shipping papers, and the offering of placards
 - e. criteria for identifying the presence of a hazardous substance radionuclide
 - f. requirements for transportation emergency response information which must accompany a shipment
 - g. requirements regarding the maximum number of packages permitted in a vehicle and the minimum separation distance between a group of packages and the vehicle operator
 - h. requirements for a Certified Driver's License with hazardous materials endorsement.

COURSE OUTLINE

- I. INTRODUCTION
- II. TRAINING REQUIRED FOR SHIPMENT OF RADIOACTIVE MATERIAL
- III. REGULATIONS PERTINENT TO TRANSPORTATION OF RADIOACTIVE MATERIAL
 - A. General information regarding the Federal Register and the Code of Federal Regulations
 - B. Specific information regarding 49 CFR
- IV. A SUGGESTED METHOD TO LOCATE SPECIFIC REGULATIONS
- V. STEP-BY-STEP GUIDE TO TRANSPORTING A RADIOPHARMACEUTICAL
 - A. Step 1: Determine if the material is regulated in transport
 - B. Step 2: Determine the primary hazard for a radiopharmaceutical
 - C. Step 3: Select the proper shipping name
 - D. Step 4: Select the authorized packaging
 - E. Step 5: Select and prepare the package label
 - F. Step 6: Assure that proper markings are on the package
 - G. Step 7: Prepare the shipping paper
 - H. Step 8: Assure that emergency response information is included with the package
 - I. Step 9: Assure that vehicle operator responsibilities are met
 - J. Demonstration of stepwise approach using ^{131}I shipment as example
- VI. SUMMARY

**DEPARTMENT OF TRANSPORTATION REGULATIONS
PERTINENT TO
NUCLEAR PHARMACY AND NUCLEAR MEDICINE PRACTICE**

by:

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INTRODUCTION

The Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) have authority to regulate the offering of radioactive material for transport. A Memorandum of Understanding delineates each agency's responsibilities. The DOT regulates carriers¹ and shipments of small quantities of radioactive material, e.g., the typical shipment from a nuclear pharmacy. The NRC is responsible for regulating shipment of special nuclear materials (containing uranium or plutonium), and large quantities of radioactive material, and for investigating accidents or incidents. The NRC also requires the licensee to comply with DOT regulations by the following statement in 10 CFR (Code of Federal Regulations) Part 71.5: *"Each licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the regulation appropriate to the mode of transport of DOT in 49 CFR Parts 170 through 185."*

The transport history of radioactive material over the past fifty years has been exemplary. There has not been a single fatality from the radioactive contents of a shipment. The regulations governing the transportation of radioactive material do work to protect the general public and transport workers from the hazards associated with radioactive material.

TRAINING REQUIRED FOR SHIPMENT OF RADIOACTIVE MATERIAL

Training in transport regulations is the key to safety. In fact, the regulations require that a training program be completed.³

A person who uses one or more of his employees in connection with the offering or transporting of a hazardous material is defined by regulations as a **Hazmat Employer**. The employee who, in the course of employment, directly affects hazardous materials transportation safety is a **Hazmat Employee**.⁴ Examples of hazmat shipping activities include, but are not limited to, packaging, preparing the shipping papers, and determining category of label. A carrier's hazmat activities include loading, affixing placards, and operating a vehicle that is transporting hazardous materials.

An employee who performs any function subject to the DOT regulations may not perform that function unless instructed in the applicable transport regulations. A new Hazmat Employee or a Hazmat Employee who changes his function may perform those functions prior to the completion of training, provided that (1) the employee is under the direct supervision of a properly trained Hazmat Employee, and (2) the training is completed within 90 days after employment or after a change in function.

Hazmat training shall include:

- General familiarization training designed to (1) provide awareness of the hazardous materials regulations, and (2) enable the employee to recognize and identify hazardous material consistent with the regulations for shipping papers, marking and labeling of packages, and placarding of vehicles.
- Function-specific training that is specifically applicable to the function of the employee.

The Hazmat Employer must insure that each Hazmat Employee is tested by appropriate means on the training topics. A record of current training shall be retained by the Hazmat Employer for as long as that employee is employed and for 90 days thereafter. The record shall include:

- the Hazmat Employee's name
- the most recent training date
- a description, copy, or location of the training materials used
- the name and address of the person providing the training
- certification that the Hazmat Employee has been trained and tested.

The Hazmat Employee shall receive training at least once in three years. Relevant training from a previous employer may be used to satisfy the requirements, provided a current record of training is obtained from the previous employer.

REGULATIONS PERTINENT TO TRANSPORTATION OF RADIOACTIVE MATERIALS

General Information regarding the Federal Register (FR) and the Code of Federal Regulations (CFR).

The CFR contains the general and permanent rules of the executive department and agencies of the federal government. The CFR is kept up to date by the individual issues of the *Federal Register*. These two publications are used together to determine the latest version of a given requirement. The CFR is divided into 50 titles, each title containing one or more volumes, representing broad areas subject to federal regulations. Each title is divided into chapters that bear the name of the issuing agency. Each chapter is subdivided into parts covering specific regulatory areas; parts are divided into sections, the basic unit of the CFR. If further breakdown is necessary it is to the paragraph level. Each volume is revised at least once each calendar year.

Specific information regarding 49 CFR.

The DOT hazardous materials regulations are located in "Title 49 Code of Federal Regulations, Transportation, Chapter I, Research and Special Programs Administration, Department of Transportation, Subchapter C, Hazardous Materials Regulations. 49 CFR is revised every October 1. This lesson uses the regulations published October 1, 1997.

Two 1997 publications of 49 CFR are commercially available. The "early bird" edition is missing requirements for a radiation protection program for transportation (Part 172 Subpart I) because the DOT had published a Directive Rule withdrawing the requirement for the radiation protection program prior to publication of the early bird edition. However, a challenge to the method by which the requirement was withdrawn required DOT to reinstate the requirement for radiation protection. It appears in the later publication of 49 CFR (1997 edition). The DOT delayed mandatory compliance with the radiation protection regulations until 1999 and simultaneously published a Notice of Rulemaking which again withdrew the requirement for these regulations, but this time using the traditional method required for rulemaking. There is no serious challenge to the elimination of the radiation protection program as originally formulated. Therefore, this lesson anticipates revocation of Part 172 Subpart I and omits requirements for radiation protection in transportation.

The parts of 49 CFR applicable to radioactive materials, i.e., packaging, shipping, and transport, include Parts 171, 172, 173, 175, 177, and 178. A brief description of each part follows (see Figure 1):

Part 171 contains the scope of regulations, definitions applicable to all hazardous materials, use of international air transport regulations, conversion factor for metric units, notification to the DOT of transportation incidents, and reporting requirement for releases of hazardous substances.

Part 172 contains the Hazardous Materials Table. This table lists the authorized shipping name with the assigned hazard class, the UN (United Nations) number, any special transport provisions, and the authorized packagings. The DOT recently added to Part 172 the requirement that a shipper must provide immediate emergency response information, mandatory hazmat training, and a radiation protection program for transport workers.

Part 173, organized by hazard class, contains definitions for each hazard class or division,⁵ along with instructions

on how to determine the primary hazard of a mixture and the packing group. The packing group further classifies the material as presenting a minimum, medium, or great danger in transportation. Packing groups used for selection of authorized packaging are also found in this part. For the primary hazard of radioactive material, packing groups are not used. Subpart I (radioactive materials) is organized as follows (see Figure 2):

- § 173.400 - 409 Scope and definitions
- § 173.410 - 419 Packaging requirements
- § 173.429 - 429 Excepted packaging
- § 173.430 - 439 Determination of Type A quantity
- § 173.440 - 449 Transport requirements
- § 173.450 - 459 Fissile materials
- § 173.460 - 469 Performance tests
- § 173.470 - 479 Permits and approvals

Part 175 contains the requirements for air carriers transporting hazardous material in commerce. These requirements are applicable to U.S. air carriers operating anywhere in the world and to foreign air carriers operating in U.S. air space.⁶

Part 177 sets forth requirements for the transport of hazardous materials by public highway. The regulations in this part apply to all highway carriers, private or common, in exclusive use or not in exclusive use.⁷ Important sections include location of shipping papers in a vehicle, the maximum number of packages in a vehicle, and the minimum separation distance between packages and the vehicle operator.

Part 178 contains packaging specifications and performance requirements. For radiopharmaceuticals, only §178.350 is relevant.

A SUGGESTED METHOD TO LOCATE SPECIFIC REGULATIONS

The hazardous materials regulations encompass over 1000 pages. Finding a specific regulation in the CFR can be frustrating and time consuming. It can be accomplished by first formulating a search question as simple and complete as possible. Then, using the **Table of Contents** and the **Index of Sections**, all possible citations should be listed. Finally, the list of citations is scanned until the appropriate regulation is found.⁸

The following case illustrates the use of the Table of Contents and Index of Sections.

A nuclear pharmacy has recently decided to use a computer program to prepare shipping papers. The employees of the nuclear pharmacy need to know several things with regard to a shipping paper: (1) Is there a minimum size requirement? (2) Is there a specified format? (3) What information must be present?

Therefore, the most direct search question is: What is a shipping paper? Definitions are found in Part 171, in the summary of the Table of Contents. The specific section for definitions is §171.8.⁹ By referring to this section, it can be noted that the definition for a shipping paper does not contain requirements of minimum size or specific format. Rather, a shipping paper can be any piece of paper as long as it contains the prescribed descriptions in §172.202, §172.203, and §172.204.

STEP-BY-STEP GUIDE TO TRANSPORTING A RADIOPHARMACEUTICAL

The regulations governing the transport of radioactive material covers all modes of transportation. They contain a wide range of controls *from* large quantity shipments that must travel on designated routes with escort vehicles, *to* the minimally regulated materials such as the household smoke detector with 0.3 microcuries of ²⁴¹Americium. The following sequence of steps maps a route through this labyrinth that is specific for radiopharmaceutical shipments transported by public highway:

CHAPTER I—RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER A—HAZARDOUS MATERIALS AND OIL TRANSPORTATION

<i>Part</i>		
106	Rulemaking procedures	7
107	Hazardous materials program procedures	12
110	Hazardous materials public sector training and planning grants	56

SUBCHAPTER B—OIL TRANSPORTATION

<i>Part</i>		
130	Oil spill prevention and response plans	65

SUBCHAPTER C—HAZARDOUS MATERIAL REGULATIONS

<i>Part</i>		
171	General information, regulations, and definitions	68
172	Hazardous materials tables and hazardous materials communications regulations	103
173	Shippers — General requirements for shipments and packagings	423
174	Carriage by rail	688
175	Carriage by aircraft	713
176	Carriage by vessel	733
177	Carriage by public highway	792
178	Specifications for packagings	813
179	Specifications for tank cars	1021
180	Continuing qualification and maintenance of packagings	1083

Figure 1. Table of Contents for 49CFR Chapter 1

Subpart I—Class 7 (Radioactive) Materials

<p>173.401 Scope.</p> <p>173.403 Definitions.</p> <p>173.410 General design requirements.</p> <p>173.411 Industrial packagings.</p> <p>173.412 Additional design requirements for Type A packages.</p> <p>173.413 Requirements for Type B packages.</p> <p>173.415 Authorized Type A packages.</p> <p>173.416 Authorized Type B packages.</p> <p>173.417 Authorized fissile materials packages.</p> <p>173.418 Authorized packages-pyrophoric Class 7 (radioactive) materials.</p> <p>173.419 Authorized packages-oxidizing Class 7 (radioactive) materials.</p> <p>173.420 Uranium hexafluoride (fissile, fissile excepted and non-fissile).</p> <p>173.421 Excepted packages for limited quantities of Class 7 (radioactive) materials.</p> <p>173.422 Additional requirements for excepted packages containing Class 7 (radioactive) materials.</p> <p>173.423 Requirements for multiple hazard limited quantity Class 7 (radioactive) materials.</p> <p>173.424 Excepted packages for radioactive instruments and articles.</p> <p>173.425 Table of activity limits-excepted quantities and articles.</p> <p>173.426 Excepted packages for articles containing natural uranium or thorium.</p> <p>173.427 Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).</p> <p>173.428 Empty Class 7 (radioactive) materials packaging.</p> <p>173.431 Activity limits for Type A and Type B packages.</p>	<p>173.433 Requirements for determining A₁ and A₂ values for radionuclides and for the listing of radionuclides on shipping papers and labels.</p> <p>173.434 Activity-mass relationships for uranium and natural thorium.</p> <p>173.435 Table of A₁ and A₂ values for radionuclides.</p> <p>173.441 Radiation level limitations.</p> <p>173.442 Thermal limitations.</p> <p>173.443 Contamination control.</p> <p>173.447 Storage incident to transportation-general requirements.</p> <p>173.448 General transportation requirements.</p> <p>173.453 Fissile materials-exceptions.</p> <p>173.457 Transportation of fissile material, controlled shipments-specific requirements.</p> <p>173.459 Mixing of fissile material packages.</p> <p>173.461 Demonstration of compliance with tests.</p> <p>173.462 Preparation of specimens for testing.</p> <p>173.465 Type A packaging tests.</p> <p>173.466 Additional tests for Type A packagings designed for liquids and gases.</p> <p>173.467 Tests for demonstrating the ability of Type B and fissile materials packagings to withstand accident conditions in transportation.</p> <p>173.468 Test for LSA-III material.</p> <p>173.469 Tests for special form Class 7 (radioactive) materials.</p> <p>173.471 Requirements for U.S. Nuclear Regulatory Commission approved packages.</p> <p>173.472 Requirements for exporting DOT Specification Type B and fissile packages.</p> <p>173.473 Requirements for foreign-made packages.</p> <p>173.474 Quality control for construction of packaging.</p> <p>173.475 Quality control requirements prior to each shipment of Class 7 (radioactive) materials.</p> <p>173.476 Approval of special form Class 7 (radioactive) materials.</p>
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Figure 2. Table of Contents for 49CFR Part 173 Subpart I

Step 1. Determine if the material is regulated in transport. The DOT defines radioactive material as material with a specific activity (activity/weight) greater than 70 Becquerels (Bq) per gram.¹⁰ A specific activity of less than 70 Bq/gram is not regulated in transport.

Step 2. Determine the primary hazard for a radiopharmaceutical.¹¹ The properties of a material may satisfy definitions for a number of hazard classes or divisions such as flammable, toxic, corrosive, compressed gas, radioactive, or poison, among others.¹² Definitions for hazard classes and divisions are found in §173.2 (see Table 1). When a material has more than one hazard it is necessary to determine the primary hazard; all the others become subsidiary hazards. A radiopharmaceutical has only the single hazard of radioactivity (Class 7).

Step 3. Select the proper shipping name¹³. Once the primary hazard is determined, the next step is selection of a shipping name authorized by the DOT. The shipping names are listed in the Hazardous Materials Table (§172.101), under column B, in Roman Type, corresponding to the primary hazard of the material.¹⁴ Shipping names for radioactive material are listed as either technical names or generic names based on the primary hazard class name, e.g., "Radioactive material." A technical name means a recognized chemical name currently used in scientific and technical journals and texts. Technical names for radioactive materials are listed for only uranium and thorium and their compounds. An example of a technical name is thorium nitrate hexahydrate. With one exception, generic names for radioactive materials combine the hazard class with the form of the material (e.g., fissile, low specific activity, surface contaminated objects, or special form).¹⁵ An example of a generic name is "Radioactive material, special form, n.o.s. (not otherwise specified)." The majority of shipments (estimated at over 95%), including shipments of radiopharmaceuticals, are not described by one of the forms. The proper shipping name is simply "Radioactive material, n.o.s."¹⁶ The proper shipping name may be in the singular or plural, lower or upper case. The selection of the proper shipping name leads the shipper to the authorized packaging under column 8A or 8B of the Hazardous Materials Table from §172.101 (see Table 2).

Step 4. Select the authorized packaging. Packaging refers to the outside container and all other necessary components to satisfy minimum requirements of the regulations. The package is the packaging plus the hazardous material.¹⁷ For quantities shipped by nuclear pharmacies, there are two types of authorized packaging: **Type A packaging** and **Excepted packaging**.

- a. **Type A packaging.** Type A packaging is intended to provide safe and economical transport for relatively small, but significant, quantities of radioactive material. Type A containers are designed to maintain their integrity under the kind of abuse or mishandling encountered in normal transport, i.e., falling from vehicles, being dropped during handling, being exposed to the weather, struck by a sharp object, or having other packages stacked on top. The specific tests required for Type A packages simulate these events. Details of performance tests are found in §173.465 and §173.466. The shipper must keep on file, for one year after the last shipment, a complete safety analysis including the details of the package design, test results, maximum gross weight, and the authorized form of the radioactive material.¹⁸

In the event of a severe accident, the Type A package may be damaged and the contents may be released. The regulations, therefore, prescribe limits, based on the relative hazard of the material that can be transported in such packages. The limits insure that in the event of a release, the risks from external radiation or contamination are low. The limits are radionuclide specific and are found in §173.435 (Table of A_1 and A_2 values). The limits are expressed as the maximum activity allowed in a Type A package for special form (A_1) and other than special form or normal form (A_2)¹⁹ (see Table 3). The value of A_1 is the maximum activity permitted in a Type A packaging for a special form material. The value of A_2 is for a material in other than special form, or sometimes referred to as normal form.

Special form material is either a nondispersible solid or a sealed capsule. The material has a very high degree of physical integrity so that if the material were released from the package, there might be a radiation hazard, but it is highly unlikely that there would be any contamination hazard.

Table 1. Definitions of Hazard Classes and Divisions.

Class No.	Division No. (if any)	Name of class or division	49 CFR reference for definitions
None		Forbidden materials	173.21
None		Forbidden explosives	173.54
1	1.1	Explosives (with a mass explosion hazard)	173.50
1	1.2	Explosives (with a projection hazard)	173.50
1	1.3	Explosives (with predominately a fire hazard)	173.50
1	1.4	Explosives (with no significant blast hazard)	173.50
1	1.5	Very insensitive explosives; blasting agents	173.50
1	1.6	Extremely insensitive detonating substances	173.50
2	2.1	Flammable gas	173.115
2	2.2	Non-flammable compressed gas	173.115
2	2.3	Poisonous gas	173.115
3		Flammable and combustible liquid	173.120
4	4.1	Flammable solid	173.124
4	4.2	Spontaneously combustible material	173.124
4	4.3	Dangerous when wet material	173.124
5	5.1	Oxidizer	173.127
5	5.2	Organic peroxide	173.128
6	6.1	Poisonous materials	173.132
6	6.2	Infectious substance (Etiologic agent)	173.134
7		Radioactive material	173.403
8		Corrosive material	173.136
9		Miscellaneous hazardous material	173.140
None		Other regulated material: ORM-D	173.144

Table 2. Excerpt from Hazardous Materials Table

§172.101 HAZARDOUS MATERIALS TABLE—Continued

(1) Sym- bole	(2) Hazardous materials descriptions and proper shipping names	(3) Hazard class or Di- vision	(4) Identifi- cation Num- bers	(5) PG	(6) Label Codes	(7) Special provisions	(8) Packaging (§173.***)			(9) Quantity limitations		(10) Vessel stow- age	
							Excep- tions (8A)	Non- bulk (8B)	Bulk (8C)	Passenger aircraft/rail (9A)	Cargo air- craft only (9B)	Loca- tion (10A)	Other (10B)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	Radioactive material, excepted package-articles manufactured from natural or depleted uranium or natural thorium.	7	UN2910	None	422, 426.	422, 426.	422, 426.	A
	Radioactive material, excepted package-instruments or articles.	7	UN2910	None	422, 424, 421.	422, 424, 421.	422, 424, 421.	A
	Radioactive material, excepted package-limited quantity of materials.	7	UN2910	None	422, 422.	422, 422.	422, 422.	A
	Radioactive material, fissile, n.o.s.	7	UN2918	7	421, 421.	421, 421.	421, 421.	A
	Radioactive material, low specific activity, n.o.s. or Radioactive material, LSA, n.o.s.	7	UN2912	7	421, 427	421, 427	421, 427	A
	Radioactive material, n.o.s.	7	UN2982	7	421, 428.	415, 416.	415, 416.	A	40, 95
	Radioactive material, special form, n.o.s.	7	UN2974	7	421, 424.	415, 416.	415, 416.	A
	Radioactive material, surface contaminated object or Radioactive material, SCO.	7	UN2913	7	421, 424, 426.	421, 427	421, 427	A

Table 3. Excerpt from Table of A₁ and A₂ Values for Radionuclides.

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225	Actinium(89)	0.6	16.2	1 x 10 ²	0.270	2.1 x 10 ³	5.8 x 10 ⁴
Ac-227		40	1080	2 x 10 ⁻⁵	5.41 x 10 ⁻⁴	2.7	7.2 x 10 ¹
Ac-228		0.6	16.2	0.4	10.8	8.4 x 10 ⁴	2.2 x 10 ⁶
Ag-105	Silver(47)	2	54.1	2	54.1	1.1 x 10 ³	3.0 x 10 ⁴
Ag-108m		0.6	16.2	0.6	16.2	9.7 x 10 ⁻¹	2.6 x 10 ¹
Ag-110m		0.4	10.8	0.4	10.8	1.8 x 10 ²	4.7 x 10 ³
Ag-111		0.6	16.2	0.5	13.5	5.8 x 10 ³	1.6 x 10 ⁵
Al-26	Aluminum(13)	0.4	10.8	0.4	10.8	7.0 x 10 ⁻⁴	1.9 x 10 ²
Am-241	Americium(95)	2	54.1	2 x 10 ⁴	5.41 x 10 ⁻³	1.3 x 10 ¹	3.4
Am-242m		2	54.1	2 x 10 ⁴	5.41 x 10 ⁻³	3.6 x 10 ¹	1.0 x 10 ¹
Am-243		2	54.1	2 x 10 ⁴	5.41 x 10 ⁻³	7.4 x 10 ⁻³	2.0 x 10 ⁻¹
Ar-37	Argon(18)	40	1080	40	1080	3.7 x 10 ³	9.9 x 10 ⁴
Ar-39		20	541	20	541	1.3	3.4 x 10 ¹
Ar-41		0.6	16.2	0.6	16.2	1.5 x 10 ⁶	4.2 x 10 ⁷
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6 x 10 ²
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	6.2 x 10 ⁴	1.7 x 10 ⁶
As-73		40	1080	40	1080	8.2 x 10 ²	2.2 x 10 ⁴
As-74		1	27.0	0.5	13.5	3.7 x 10 ³	9.9 x 10 ⁴
As-76		0.2	5.41	0.2	5.41	5.8 x 10 ⁴	1.6 x 10 ⁶
As-77		20	541	0.5	13.5	3.9 x 10 ⁴	1.0 x 10 ⁶
At-211	Astatine(85)	30	811	2	54.1	7.6 x 10 ⁴	2.1 x 10 ⁶
Au-193	Gold(79)	6	162	6	162	3.4 x 10 ⁴	9.2 x 10 ⁵
Au-194		1	27.0	1	27.0	1.5 x 10 ⁴	4.1 x 10 ⁵
Au-195		10	270	10	270	1.4 x 10 ²	3.7 x 10 ³
Au-196		2	54.1	2	54.1	4.0 x 10 ³	1.1 x 10 ⁵
Au-198		3	81.1	0.5	13.5	9.0 x 10 ³	2.4 x 10 ⁵
Au-199		10	270	0.9	24.3	7.7 x 10 ³	2.1 x 10 ⁵

Therefore, larger quantities can be typically shipped in a Type A container (§173.403, §173.469). The shipper of a special form source must have on file for one year after the last shipment a valid Certification of Competent Authority or complete safety analysis demonstrating compliance with special form tests. (§173.476).

Activities in excess of the Type A package limits must be packaged in the accident-tested Type B package.²⁰

- b. **Excepted packaging.** Excepted packages may only contain quantities of radioactive material that are so small that the potential radiological hazard that might pertain during transport is insignificant. There are no test requirements for excepted packaging. Therefore, it must be assumed that in any accident the package may fail completely and the contents may be dispersed. The quantity permitted in an excepted package is a very small fraction of the quantity permitted in a Type A package: $10^{-3} A_2$ for solid forms or $10^{-4} A_2$ for liquids or gases (see Table 4). Because of the limited quantity of material present, the shipment of an excepted package is given broad relief from transport regulations. The exceptions include requirements for shipping papers, labeling, and marking. The authorized packaging is any strong, tight packaging meeting the general design requirement of §173.410. Other requirements for the excepted packaging include the following:²¹

- The radiation levels at any point on the external surface does not exceed 0.5 mrem/hr;
- There is no significant removable contamination on the external surface of the excepted package;²²
- The outside of the inner packaging or, if there is no inner packaging, the outside of the packaging itself is marked "Radioactive";
- The following certification notice, with the name of the consignor or consignee, is enclosed in or on the package, included with the packing list, or otherwise forwarded with the package:²³ *"This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN 2910."*

For the shipment of an excepted package, the proper shipping name is changed to "Radioactive material, excepted package-limited quantity of material." Examples of excepted package-limited quantity of material are a household smoke detector or serum vials or syringes returned to the nuclear pharmacy with only a residual amount of activity.

With the selection of the proper shipping name and an authorized packaging, the primary safety issues of transport (containment and effective shielding) have been accomplished. The next step is communicating the presence of radioactive material to carriers, consignees, and emergency service personnel. This information is in the form of shipping papers, package marking and labels, and placards for vehicles.

Step 5. Select and prepare the package label. The DOT requires the use of one of three label categories to identify the radiation hazard from a Type A package: Radioactive White-I, Radioactive Yellow-II, and Radioactive Yellow-III. Carriers use the label category to guide their handling and storage practices. Yellow labels generally indicate that limitations are placed by regulations upon how these packages are stowed in a vehicle or stored before transport to ensure radiation safety. The selection of the applicable label category is based on the measurement of radiation level at the surface of the package and at one meter from each point on the external surface of the package using a properly calibrated instrument appropriate to the type of ionizing radiation and the package size.²⁴

The radiation level at one meter is defined as the transport index (TI) of the package expressed as a dimensionless number rounded up to the next tenth of a decimal.²⁵ The TI is used as a carrier control number that provides a means of radiation protection for transport workers. The TI limits the number of packages permitted in a vehicle and establishes the minimum separation distance between packages and the vehicle operator.²⁶ The label categories are as follows (see Table 5):

Category I - White, in which the maximum radiation level at the surface of the package is not more than 0.5 mrem/hr and the TI does not exceed 0.05.

Table 4. Activity Limits for Limited Quantities, Instruments, and Articles.

Nature of contents	Instruments and articles		Materials package limits ¹
	Limits for each instrument or article ¹	Package limits ¹	
Solids:			
Special form	$10^{-2}A_1$	A_1	$10^{-3}A_1$
Normal form	$10^{-2}A_2$	A_2	$10^{-3}A_2$
Liquids:			
Tritiated water:			
<0.0037 TBq/liter (0.1 Ci/L).....			37 TBq (1,000 Ci)
0.0037 TBq to 0.037 TBq/L (0.1Ci to 1.0 Ci/L)			3.7 TBq (100 Ci)
>0.037 TBq/L (1.0 Ci/L)			0.037 TBq (1.0 Ci)
Other Liquids.....	$10^{-3}A_2$	$10^{-1}A_2$	$10^{-4}A_2$
Gases:			

Table 5. Label Categories for Packages Containing Radioactive Material.

Transport index	Maximum radiation level at any point on the external surface	Label category ¹
0 ²	Less than or equal to 0.005 mSv/h (0.5 mrem/h)	WHITE-I.
More than 0 but not more than 1.....	Greater than 0.005 mSv/h (0.5 mrem/h) but less than or equal to 0.5 mSv/h (50 mrem/h)	YELLOW-II.
More than 1 but not more than 10.....	Greater than 0.5 mSv/h (50 mrem/h) but less than or equal to 2 mSv/h (200 mrem/h)	YELLOW-III.
More than 10.....	Greater than 2 mSv/h (200 mrem/h) but less than or equal to 10 mSv/h (1,000 mrem/h)	YELLOW-III (Must be shipped under exclusive use provisions; see 173.441(b) of this subchapter).

¹ Any package containing a "highway route controlled quantity" (§ 173.403 of this subchapter) must be labelled as RADIOACTIVE YELLOW-III.

² If the measured TI is not greater than 0.05, the value may be considered to be zero.

Category II - Yellow, in which the radiation level at the surface exceeds the limit for Category 1 - White, but does not exceed 50 mrem/hr at the surface and the TI does not exceed 1.0.

Category III - Yellow, in which the radiation level at the package surface exceeds the limit for Category II - Yellow, but does not exceed 200 mrem/hr and the TI does not exceed 10.0.²⁷

The highest category of label required must be applied to the package, as determined by either the surface or TI measurements. For example, a package with a TI of 0.8 and a maximum surface radiation of 60 mrem/hr must bear a Radioactive Yellow-III label. Correct labeling is essential and regulated by the federal government. The radioactive label describes the radiation hazard outside the package. Therefore, it is inappropriate to label a package with a Radioactive Yellow-II label when a Radioactive White-I label is required (over labeling) as it is to label a package Radioactive White-I when a Radioactive Yellow-II label is required (under labeling).²⁸

Each Type A package is required to have two radioactive labels of the same category affixed on opposite sides of the package (do not label the bottom of the package). The following information must be entered on the label:

Contents: The name or symbol of each radionuclide in the package.

Activity: The total activity in the package in SI Units (Becquerels) at the time of offering to a carrier for transport

Transport

Index: The highest radiation level of the external surface at a distance of one meter (only required on Radioactive Yellow-II and Radioactive Yellow-III categories).

The maximum radiation levels on the surface of a package for transport in private, contract, or common carriage (other than exclusive use²⁹) may not exceed 200 mrem/hr or a TI greater than 10.0.³⁰ If offered for air transport, the maximum TI on a package or overpack³¹ for transportation on a passenger-carrying aircraft is 3.0.³²

Step 6. Assure that proper markings are on the package. The exterior of the package must be marked within six inches of the radioactive label with the proper shipping name, Radioactive material, n.o.s., and the UN number, UN 2982 (see Step 7 for explanation of the UN number). Except for air shipments, a package containing a liquid form of radioactive material must bear two orientation arrows on opposite sides of the package pointing in the direction of the container closures (see Figure 3).

When a hazardous substance³⁴ radionuclide is present, the package must be marked with "RQ" (reportable quantity) near the proper shipping name. The hazardous substance radionuclides are listed in Appendix A to §172.101, Table 2. If the quantity in one package equals or exceeds the specified limit, the package contains an Environmental Protection Agency-defined hazardous substance. While most RQ values are generally quite large, an initial check against the listed values must be made for each radionuclide shipped. An example of a hazardous substance commonly shipped by a nuclear pharmacy is ¹³¹Iodine (¹³¹I); the RQ for ¹³¹I is 10 millicuries (0.00037 Tbq) (see Table 6). Therefore, a package containing at least 10 millicuries of ¹³¹I must be marked "RQ" in association with the proper shipping name (i.e., Radioactive material, n.o.s.). If a release of a hazardous substance occurs during transportation, the carrier must immediately notify the National Response Center at (800) 424-8802 or (202) 267-2675.³⁵

The authorized specification marking for a Type A package must be in a minimum type size of 1/2 inches as follows: USA DOT 7A Type A RADIOACTIVE MATERIAL.³⁶

All package labels and markings must be visible during transportation. As has been noted previously, two radioactive labels of the same type are placed on opposite sides, one within six inches of the proper shipping name and UN number.

Marking of Proper shipping name, UN number, identification of a Hazardous Substance and Packaging specification and label placement

Radioactive Material N.O.S.

UN 2982 RQ



USA DOT 7A Type A Radioactive Material

Figure 3

Table 6. Excerpt from Table which lists Reportable Quantities for Radionuclides.

(1)—Radionuclide	(2)—Atomic Number	(3)—Reportable Quantity (RQ) Ci (TBq)	(1)—Radionuclide	(2)—Atomic Number	(3)—Reportable Quantity (RQ) Ci (TBq)
Iodine-121	53	100 (3.7)	Lutetium-173	71	100 (3.7)
Iodine-123	53	10 (.37)	Lutetium-174	71	10 (.37)
Iodine-124	53	0.1 (.0037)	Lutetium-174m	71	10 (.37)
Iodine-125	53	0.01 (.00037)	Lutetium-176	71	1 (.037)
Iodine-126	53	0.01 (.00037)	Lutetium-176m	71	1000 (37)
Iodine-128	53	1000 (37)	Lutetium-177	71	100 (3.7)
Iodine-129	53	0.001 (.000037)	Lutetium-177m	71	10 (.37)
Iodine-130	53	.1 (.037)	Lutetium-178	71	1000 (37)
Iodine-131	53	0.01 (.00037)	Lutetium-178m	71	1000 (37)
Iodine-132	53	10 (.37)	Lutetium-179	71	1000 (37)
Iodine-132m	53	10 (.37)	Magnesium-28	12	10 (.37)
Iodine-133	53	0.1 (.0037)	Manganese-51	25	1000 (37)
Iodine-134	53	100 (3.7)	Manganese-52	25	10 (.37)
Iodine-135	53	10 (.37)	Manganese-52m	25	1000 (37)
Iridium-182	77	1000 (37)	Manganese-53	25	1000 (37)
Iridium-184	77	100 (3.7)	Manganese-54	25	10 (.37)
Iridium-185	77	100 (3.7)	Manganese-56	25	100 (3.7)
Iridium-186	77	10 (.37)	Mendelevium-257	101	100 (3.7)
Iridium-187	77	100 (3.7)	Mendelevium-258	101	1 (.037)
Iridium-188	77	10 (.37)	Mercury-193	80	100 (3.7)
Iridium-189	77	100 (3.7)	Mercury-193m	80	10 (.37)
Iridium-190	77	10 (.37)	Mercury-194	80	0.1 (.0037)
Iridium-190m	77	1000 (37)	Mercury-195	80	100 (3.7)
Iridium-192	77	10 (.37)	Mercury-195m	80	100 (3.7)
Iridium-192m	77	100 (3.7)	Mercury-197	80	1000 (37)
Iridium-194	77	100 (3.7)	Mercury-197m	80	1000 (37)
Iridium-194m	77	10 (.37)	Mercury-199m	80	1000 (37)
Iridium-196	77	1000 (37)	Mercury-203	80	10 (.37)
Iridium-195m	77	100 (3.7)	Molybdenum-101	42	1000 (37)
Iron-52	26	100 (3.7)	Molybdenum-90	42	100 (3.7)
Iron-55	26	100 (3.7)	Molybdenum-93	42	100 (3.7)
Iron-59	26	10 (.37)	Molybdenum-93m	42	10 (.37)
Iron-60	26	0.1 (.0037)	Molybdenum-99	42	100 (3.7)
Krypton-74	36	10 (.37)	Neodymium-136	60	1000 (37)
Krypton-76	36	10 (.37)	Neodymium-138	60	1000 (37)
Krypton-77	36	10 (.37)	Neodymium-139	60	1000 (37)
Krypton-79	36	100 (3.7)	Neodymium-139m	60	100 (3.7)
Krypton-81	36	1000 (37)	Neodymium-141	60	1000 (37)
Krypton-83m	36	1000 (37)	Neodymium-147	60	10 (.37)
Krypton-85	36	1000 (37)	Neodymium-149	60	100 (3.7)
Krypton-85m	36	100 (3.7)	Neodymium-151	60	1000 (37)
Krypton-87	36	10 (.37)	Neptunium-232	93	1000 (37)
Krypton-88	36	10 (.37)	Neptunium-233	93	1000 (37)
Lanthanum-131	57	1000 (37)	Neptunium-234	93	10 (.37)
Lanthanum-132	57	100 (3.7)	Neptunium-235	93	1000 (37)
Lanthanum-135	57	1000 (37)	Neptunium-236 (1.2 E 5 yr)	93	0.1 (.0037)
Lanthanum-137	57	10 (.37)	Neptunium-236 (22.5 hr)	93	100 (3.7)
Lanthanum-138	57	1 (.037)	Neptunium-237	93	0.01 (.00037)
Lanthanum-140	57	10 (.37)	Neptunium-238	93	10 (.37)
Lanthanum-141	57	1000 (37)	Neptunium-239	93	100 (3.7)
Lanthanum-142	57	100 (3.7)	Neptunium-240	93	100 (3.7)
Lanthanum-143	57	1000 (37)	Nickel-56	28	10 (.37)
Lead-195m	82	1000 (37)	Nickel-57	28	10 (.37)
Lead-198	82	100 (3.7)	Nickel-59	28	100 (3.7)
Lead-199	82	100 (3.7)	Nickel-63	28	100 (3.7)
Lead-200	82	100 (3.7)	Nickel-65	28	100 (3.7)
Lead-201	82	100 (3.7)	Nickel-66	28	10 (.37)
Lead-202	82	1 (.037)	Niobium-88	41	100 (3.7)
Lead-202m	82	10 (.37)	Niobium-89 (122 min)	41	100 (3.7)
Lead-203	82	100 (3.7)	Niobium-89 (66 min)	41	100 (3.7)
Lead-205	82	100 (3.7)	Niobium-90	41	10 (.37)
Lead-209	82	1000 (37)	Niobium-93m	41	100 (3.7)
Lead-210	82	0.01 (.00037)	Niobium-94	41	10 (.37)

Step 7. Prepare the shipping paper. Considerable confusion exists over the definition and specifications of a shipping paper. Some people confuse a technical data sheet with a shipping paper; some confuse a packing slip with a shipping paper; some believe that a shipping paper must be of a definite size and format. However, the regulations define a shipping paper not by size, not by any specific format, but by the information vital to emergency responders in a transportation incident. The following descriptions are necessary to initiate protective actions for safety of responders and the general public:

- The proper shipping name that describes the material in a general way
- The hazard class number, 7, assigned to the radioactive material hazard
- The United Nations number which is a four-digit number, preceded by "UN", assigned to a proper shipping name, used to guide emergency responders during the initial phase of a transportation incident involving hazardous materials. The guidance is found in a guidebook published by the DOT. For Radioactive material, n.o.s., the number is UN 2982
- The identity of each radionuclide in the package (abbreviations may be used)
- The total activity in SI units (e.g., Terabecquerels (TBq), Gigabecquerels (GBq) or Megabecquerels (MBq) of the radioactive content present at the time of offering for transportation; customary units (Curies, millicuries, microcuries) may also be used if placed after the required SI units and enclosed in parentheses, e.g., 37 GBq (1 Ci)
- The category of the label on the package
- The transport index for Radioactive Yellow-II or Radioactive Yellow-III labels only (the abbreviation TI is permitted)
- The physical and chemical form of the radioactive contents. The physical forms are solid, liquid, and gas; the chemical form is a name that describes the chemical structure of the material, e.g., sodium iodide (a generic name is acceptable, e.g., inorganic salt, organic compound, etc.)
- Emergency response telephone number. A person who presents a hazardous material for transportation must provide a 24-hour emergency response telephone number. The telephone number is for use if there is an incident involving the hazardous material. The telephone number must be monitored at all times while the material is in transit by a person who has knowledge of the hazards and incident mitigation information, or has immediate access to a person who possesses such knowledge and information and is entered on the shipping paper in a clearly visible location and identified by "EMERGENCY CONTACT." (An emergency response telephone number is not needed when shipping excepted packages.)

The information is organized into the basic description followed by the remainder of the required information (see Figure 4). The basic description must appear first and consists of the proper shipping name, the hazard class and "UN" number, in that order without variation. **Nothing should be added to this description and the sequence must not be changed.**³⁷ For a shipment that contains a hazardous substance radionuclide, the additional entry of "RQ" must appear immediately before or after the basic shipping description as follows:³⁸

**RQ Radioactive material, n.o.s., 7, UN 2982, or
Radioactive material, n.o.s., 7, UN 2982 RQ**

While the basic description must be in a prescribed sequence, the additional information does not. Additional entries may be added if not inconsistent with the required descriptions. Abbreviations should not be used unless specifically authorized by regulations. The commonly approved abbreviations pertain to the radionuclide, e.g., ¹³¹I, and the quantity of radioactivity, e.g., 37 MBq.

The shipper must declare that the material is offered in accordance with all applicable regulations by printing on the shipping paper, over his signature, a certification of compliance. The regulations contain a number of acceptable variations. The following example is the most commonly used for highway transportation:

**SHIPPING PAPER AND NOTIFICATION FOR LOADING OF
DANGEROUS GOODS RADIOACTIVE MATERIALS (PART CR)**

2 Aircraft / Truck Copy
 Yellow III
 Check Box for Placarding

PRESS HARD—10 PART FORM—USE BALL POINT PEN ONLY

Pg of Pgs	Proper Shipping Name		Class	UN #	Pkg. Group	Subsidiary Risks	Quantity & Type of Packing	Pkg Inst
	Radioactive Material n.o.s.		7	UN2982	RQ			
Radioisotope (Product Code)	Phys & Chemical Form	Activity	Label Category	TI	Box Dimension (If Applicable)	Tracking #	Container # (Fully Comp. In Out)	
I-131	Liquid/salt	0.37GBq	Radioactive Yellow II	TI	0.8			
Origin	Dest	Shipment Type (Delete Non-Applicable)	This Shipment is Within The Limitations Prescribed For: (Delete Non-Applicable)		Remarks/Approvals/Authorizations			
		Non-Radioactive	Radioactive	Passenger Aircraft	Cargo Aircraft Only			
<p><small>IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS OR TREATMENT. I HEREBY DECLARE THAT THE CONTENTS OF THIS CONSIGNMENT ARE FULLY AND ACCURATELY DESCRIBED ABOVE BY PROPER SHIPPING NAME AND ARE CLASSIFIED, PACKAGED, MARKED AND LABELLED AS REQUIRED AND ARE IN FULL RESPECT IN PROPER CONDITION FOR TRANSPORT ACCORDING TO THE APPLICABLE INTERNATIONAL AND NATIONAL GOVERNMENTAL REGULATIONS.</small></p>								
Shippers Name and Address			Place/Date			Recipients Name and Address		
Signature 			Title <u>Shipper</u>					

Typewritten Signature Acceptable

Figure 4. Example of Completed Shipping Paper.

"This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper conditions for transportation according to the applicable regulations of the Department of Transportation."

The signature must be legibly signed by a principal, officer, partner or employee of the shipper or his agent; it may be signed manually, by typewriter, or by other mechanical means.

The re-authorization of the Hazardous Materials Safety Act includes a requirement for a 90 day retention of shipping papers by shipper. Although DOT has yet to amend its regulations to reflect the record retention requirement, ignorance of the law is no excuse, i.e., maintain shipping papers for at least 90 days.

Step 8. Assure that emergency response information is included with the package. No person may offer a hazardous material for transportation or transport a hazardous material unless emergency response information is immediately available for use by responders to an incident. The information may be in a document accompanying the shipping paper or on the shipping paper. The information must be available for use away from the package. As a minimum, the information must include:

- the basic shipping description;
- immediate hazards to health;
- risks of fire or explosion;
- immediate precautions to be taken in the event of an incident;
- immediate methods for handling fires;
- initial methods for handling spills;
- preliminary first aid measures

The requirement for emergency response information is satisfied by the "1996 North American Emergency Response Guidebook."⁴⁰ (see Figure 5)

Step 9. Assure that vehicle operator responsibilities are met. Each carrier who transports a hazardous material shall maintain information regarding the hazardous material in the same manner as prescribed for shipping papers.

The regulations for the transport of radioactive material by public highway are found in Part 177. Sections specific to deliveries of radiopharmaceuticals are:

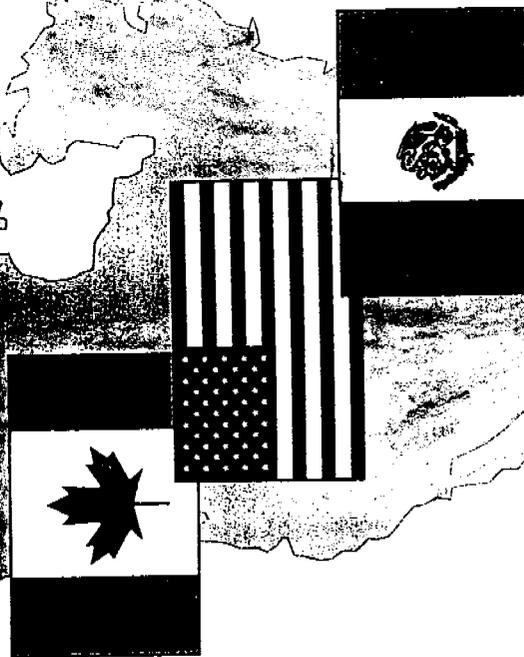
- | | |
|--------------|--|
| § 177.800 | Purpose and scope |
| § 177.810 | Vehicle tunnels |
| § 177.816 | Driver training |
| § 177.8817 | Shipping papers |
| § 177.834(a) | Securing against movement |
| § 177.842 | Radioactive material; TI limit and separation distance |
| § 177.843 | Contamination of vehicles |
| § 177.870 | Passenger carrying vehicles (Taxi) |

Compliance with the hazardous materials regulations is applicable to the acceptance and transportation of hazardous material by private, common, or contract carriers by motor vehicle. Along with awareness and function-specific hazmat training, each Hazmat Employee who will operate a motor vehicle must be trained in the applicable requirements of the Federal Motor Carrier Safety Regulations (49 CFR Parts 390 through 397).

An operator of a vehicle transporting one or more packages labeled Radioactive Yellow-III must affix four radioactive placards on the vehicle, i.e., facing front, facing rear, and one on each side. The vehicle operator must have a valid Certified Drivers license (CDL) with a hazmat endorsement.

The carrier may not transport a quantity of radioactive material that requires a Type A package unless it is accompanied by a shipping paper. The shipping paper must be accessible and visible. Specifically, the driver shall (1) clearly distinguish the shipping paper, if it is a carrier with other shipping papers or other papers of any kind, by either distinctively tabbing or by having it appear first; and (2) store the shipping paper, when the driver is at the controls, within his immediate reach while restrained by the lap belt; and

1996 NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK



A GUIDEBOOK
FOR FIRST RESPONDERS DURING
THE INITIAL PHASE OF A
HAZARDOUS MATERIALS/DANGEROUS GOODS
INCIDENT

ID No.	Guide No.	Name of Material
2979	162	Uranium metal, pyrophoric
2980	162	Uranyl nitrate, hexahydrate, solution
2981	162	Uranyl nitrate, solid
2982	163	Radioactive material, n.o.s.
2983	129P	Ethylene oxide and Propylene oxide mixture, with not more than 30% Ethylene oxide
2983	129P	Propylene oxide and Ethylene oxide mixture, with not more than 30% Ethylene oxide
2984	140	Hydrogen peroxide, aqueous solution, with not less than 8% but less than 20% hydrogen peroxide
2985	155	Chlorosilanes, flammable, corrosive, n.o.s.
2985	155	Chlorosilanes, n.o.s.
2986	155	Chlorosilanes, corrosive, flammable, n.o.s.
2986	155	Chlorosilanes, n.o.s.
2987	156	Chlorosilanes, corrosive, n.o.s.
2987	156	Chlorosilanes, n.o.s.
2988	139	Chlorosilanes, n.o.s.
2988	139	Chlorosilanes, water-reactive, flammable, corrosive, n.o.s.
2989	133	Lead phosphite, dibasic
2990	171	Aircraft evacuation slides
2990	171	Life-saving appliances, self-inflating
2991	131	Carbamate pesticide, liquid, poisonous, flammable
2991	131	Carbamate pesticide, liquid, toxic, flammable
2992	151	Carbamate pesticide, liquid, poisonous

Page 71

GUIDE 163 RADIOACTIVE MATERIALS (LOW TO HIGH LEVEL RADIATION)

POTENTIAL HAZARDS

HEALTH

- Radiation presents minimal risk to transport workers, emergency response personnel, and the public during transportation accidents. Packaging durability is related to potential hazards of material.
- Undamaged packages are safe; contents of damaged packages may cause external and/or internal radiation exposure.
- Type A packages (cartons, boxes, drums, articles, etc.) identified as "Type A" by marking on packages or by shipping papers contain non-life endangering amounts. Partial releases might be expected if "Type A" packages are damaged in moderately severe accidents.
- Type B packages (large and small, usually metal) identified as "Type B" by marking on packages or by shipping papers contain potentially life endangering amounts. Because of design, evaluation, and testing of packages, life endangering releases are not expected in accidents involving "Type B" packages except those of utmost severity.
- Radioactive White-I labels indicate radiation levels outside undamaged packages are very low (less than 0.005 mSv/h (0.5 mrem/h)).
- Radioactive Yellow-II and Yellow-III labeled packages have higher radiation levels. The transport index (TI) on the label identifies the maximum radiation level in mrem/h one meter from the package.
- Some radioactive materials cannot be detected by commonly available instruments.
- Water from cargo fire control may cause pollution.

FIRE OR EXPLOSION

- Some of these materials may burn, but most do not ignite readily.
- Radioactivity does not change flammability or other properties of materials.
- Type B packages are designed and evaluated to withstand total engulfment in flames at temperatures of 800°C (1475°F) for a period of 30 minutes.

PUBLIC SAFETY

- CALL Emergency Response Telephone Number on Shipping Paper first. If Shipping Paper not available or no answer, refer to appropriate telephone number listed on the inside back cover.
- Priorities for rescue, life-saving, first aid, and control of fire and other hazards are higher than the priority for measuring radiation levels.
- Radiation Authority must be notified of accident conditions, and is usually responsible for radiological decisions.
- Isolate spill or leak area immediately for at least 25 to 50 meters (80 to 160 feet) in all directions. Stay upwind. Keep unauthorized personnel away.
- Detain or isolate uninjured persons or equipment suspected to be contaminated, delay decontamination and cleanup until instructions are received from Radiation Authority.

PROTECTIVE CLOTHING

- Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection against internal radiation exposure, but not external radiation exposure.

EVACUATION

- Large Spill
- Consider initial downwind evacuation for at least 100 meters (330 feet).
- Fire
- When a large quantity of this material is involved in a major fire, consider an initial evacuation distance of 300 meters (1000 feet) in all directions.

Page 274

Figure 5. Excerpts from Emergency Response Guidebook.

either readily visible to a person entering the driver's compartment or in a holder that is mounted to the inside of the door on the driver's side; or when the driver is not at the vehicle controls, the shipping paper shall be either in the holder or placed on the driver's seat.

The packages must be secured in the vehicle against movement under conditions normally incident to transportation. The number of packages in any transport vehicle must be limited so that the total TI determined by adding together the TI number on the labels on the individual packages does not exceed 50. In addition, packages labeled Radioactive Yellow-II or Radioactive Yellow-III may not be placed in a transport vehicle closer than the minimum distances given in §177.842 to any area continuously occupied by passengers or employees (or from the dividing partition of the cargo compartment.) (see Table 7).

Example of how to apply the nine-step approach for shipment of a package containing a radiopharmaceutical.

To illustrate how the nine steps can be applied to an actual shipping situation in a nuclear pharmacy, consider the shipment of a vial containing 1.1 GBq (30 mCi) of ¹³¹I sodium iodide solution by public highway to a local hospital:

Step 1. Determine if the material is regulated in transport. The specific activity of the ¹³¹I radiopharmaceutical is obviously very high, much greater than the 70 Bq/gram (0.002 μCi/gram) specified limit. The material is therefore regulated as a radioactive material.

Step 2. Determine the primary hazard for a radiopharmaceutical. A radiopharmaceutical has the single hazard class 7 (radioactive material).

Step 3. Select the proper shipping name. A radiopharmaceutical is not manufactured and tested to specifications for special form; it is normal form material. The specific activity is too great for Low Specific Activity or LSA; it is not a nonradioactive substance contaminated with radioactive material (Surface Contaminated Object or SCO); neither does it contain a fissile radionuclide of uranium or plutonium. Therefore, the only appropriate choice for the proper shipping name is Radioactive material, n.o.s.

Step 4. Select the authorized packaging. Information on authorized packaging is found in Column 8 of the Hazardous Materials Table (§172.101). For a radiopharmaceutical with the proper shipping name Radioactive material, n.o.s., the citations (§173.421 under column 8A (Excepted Packaging) and (§173.415 under column 8B (Specified Packaging) are the applicable references.

The maximum activity for ¹³¹I that may be shipped as a limited quantity in an excepted package is found by the reference to Table 7 of §173.425. For other than special form (normal form) of radioactive material, the formula for calculating the maximum limited quantity activity of ¹³¹I permitted as a liquid in an excepted package is $10^{-4} A_2$ (¹³¹I). The A_2 value for ¹³¹I found in §173.435 is 0.5 TBq (13.5 Ci). When 0.5 TBq is substituted for A_2 (¹³¹I), then $10^{-4} A_2$ (¹³¹I) = 50 MBq (1.35 mCi). The activity of ¹³¹I to be shipped is greater than this calculated limited quantity amount, so it must be shipped in a Type A packaging.

Only a Type A packaging with a valid safety analysis (demonstrating compliance with the design requirement and performance tests) should be used. The safety analysis must be kept on file for one year after the last use.

Step 5. Select and prepare the package label. Using a properly calibrated meter appropriate for the type of radiation emitted from the radiopharmaceutical being shipped (¹³¹I), the radiation level is measured at each point on the external surface of the package and at one meter from the package. If, for example, the maximum radiation level of the package containing ¹³¹I is 45 mrem/hr at the surface and 0.76 mrem/hr at one meter, then the category of label required for the package is Radioactive Yellow-II. The information required on the label is the name or symbol of the radionuclide (¹³¹I), the activity of the ¹³¹I at the time of offering for transportation, and the TI (0.8). Two labels are placed on opposite sides of the package. Two orientation labels ("arrows") are also required on opposite sides.

Table 7. Required Separation Distances for Packages Containing Radioactive Materials While in Transit.

Total transport index	Minimum separation distance in meters (feet) to nearest undeveloped film in various times of transit				Minimum distance in meters (feet) to area of persons, or minimum distance in meters (feet) from dividing partition of cargo compartments
	Up to 2 hours	2-4 hours	4-8 hours	8-12 hours	
None	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
0.1 to 1.0	0.3 (1)	0.6 (2)	0.9 (3)	1.2 (4)	1.5 (5)
1.1 to 5.0	0.9 (3)	1.2 (4)	1.8 (6)	2.4 (8)	3.4 (11)
5.1 to 10.0	1.2 (4)	1.8 (6)	2.7 (9)	3.4 (11)	4.6 (15)
10.1 to 20.0	1.5 (5)	2.4 (8)	3.7 (12)	4.9 (16)	6.7 (22)
20.1 to 30.0	2.1 (7)	3.0 (10)	4.6 (15)	6.1 (20)	8.8 (29)
30.1 to 40.0	2.4 (8)	3.4 (11)	5.2 (17)	6.7 (22)	10.1 (33)
40.1 to 50.0	2.7 (9)	3.7 (12)	5.8 (19)	7.3 (24)	11.0 (36)

Note: The distance in this table must be measured from the nearest point on the nearest packages of Class 7 (radioactive) material.

§177.842 Class 7 (radioactive) material.

(a) The number of packages of Class 7 (radioactive) materials in any transport vehicle or storage location must be limited so that the total transport index number does not exceed 50. The total transport index of a group of packages and overpacks is determined by adding together the transport index number on the labels on the individual packages and overpacks in the group. This provision does not apply to exclusive use shipments described in §§ 173.441(b), 173.457, and 173.427 of this subchapter.

(b) Packages of Class 7 (radioactive) material bearing "RADIOACTIVE YELLOW-II" or "RADIOACTIVE YELLOW-III" labels may not be placed in a transport vehicle, storage location or in any other place closer than the distances shown in the following table to any area which may be continuously occupied by any passenger, employee, or animal, nor closer than the distances shown in the table to any package containing undeveloped film (if so marked), and must conform to the following conditions:

(1) If more than one of these packages is present, the distance must be computed from the following table on the basis of the total transport index number determined by adding together the transport index number on the labels on the individual packages and overpacks in the vehicle or storeroom.

(2) Where more than one group of packages is present in any single storage location, a single group may not have a total transport index greater than 50. Each group of packages must be handled and stowed not closer than 6 meters (20 feet) (measured edge to edge) to any other group. The following table is to be used in accordance with the provisions of paragraph (b) of this section:

Step 6. Assure that proper markings are on the package. The package is marked with:

- The proper shipping name, Radioactive material, n.o.s. (within 6 inches of the label)
- The UN number, UN2982
- “RQ” in association with the proper shipping name (the reportable quantity for ^{131}I is 10 mCi)
- The specification marking for the package (For Type A packaging: USA DOT 7A Type A RADIOACTIVE MATERIAL)

Also include the name and address of the nuclear pharmacy and the consignee.

Step 7. Prepare the shipping paper. The required shipping description is as follows:

RQ Radioactive material, n.o.s., 7, UN2982
 ^{131}I , liquid, inorganic salt
Radioactive Yellow II, TI 0.8

Transportation emergency telephone number

Include the following statement:

“This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.” (Signature)

Step 8. Assure that emergency response information is included with the package. Provide accident mitigation information, e.g., a material safety data sheet, or the page with guide 162 from the DOT Emergency Response Guidebook, or ensure that carrier has a copy of the DOT Guidebook in the vehicle.

Step 9. Assure that vehicle operator responsibilities are met. Place the package in the vehicle no closer than the minimum distance to the vehicle operator as stated in §177.842. In this example, if the package containing ^{131}I is the only one being carried in the vehicle, the minimum separation distance is one foot. The shipping paper is placed on the seat next to the driver, within arms reach with the seat restraint engaged.

Taking the example one step further, assume that upon administration of the ^{131}I dose at the local hospital, the vial contains only residual ^{131}I . In order to return the vial to the nuclear pharmacy, the following items must be considered:

- The specific activity is still greater than 70 Bq/gram.
- The hazard class remains class 7.
- The quantity present is now likely to be less than the maximum permitted for the limited quantity amount (calculated above) at 50 MBq (1.35 mCi). A measurement should be taken to confirm this assumption.
- The requirements of an excepted package in §173.421 should be reviewed.

If all conditions for a limited quantity are satisfied, then the package is excepted from specified requirements for packaging, marking, labeling, and shipping paper (including emergency telephone number and accident mitigation information). In this situation, the following notice, found in §173.422, is placed on or in the package, or on paperwork accompanying the package:

“This package conforms to the conditions and limitations specified in 49 CFR §173.421 for radioactive materials, excepted package-limited quantity of material, UN2910.”

This notice must include the name of the consignor or consignee.

SUMMARY

Transport regulations governing the radiopharmaceutical shipments insure safety to the public, the environment, and property. When radiopharmaceuticals are properly packaged, marked, labeled, and accurately described, the radiopharmaceutical shipment is a hazardous materials only by virtue of its classification by the Department of Transportation, not by its presence in the transport system.

CITATIONS

1. 171.1 - Applicability of 49 CFR
2. Not used.
3. Part 172 - Subpart H
4. 171.8 - Hazmat Employee definition
5. 173.2 - Hazard classes and divisions definition
6. 175.5(a) - The applicability of 49 CFR to commercial air transport
7. 173.403 - Exclusive use
8. DOT provides a toll free service (1-800-467-4922) to answer questions on 49 CFR.
9. Definitions of terms for radioactive materials are in 173.403.
10. 173.403 - Radioactive material definition
11. 171.8 - Primary hazard definition.
12. The hazard class of a material is indicated by its class or division number. Definitions for hazard classes and divisions are referenced in 173.2.
13. 172.101 (c) - How to select a proper shipping name
14. 171.8 - Proper shipping name definition
15. The definition for each form is found in 173.403. The proper shipping names incorporating the form of the material include: Radioactive material, fissile, n.o.s.—a material containing fissionable uranium or plutonium; Radioactive material, low specific activity or LSA, n.o.s.—a material such as radioactive waste with a low ratio of activity to weight; Radioactive material, surface contaminated objects or SCO—a nonradioactive article contaminated with radioactive material; and, Radioactive material, special form, n.o.s.—a material tested and certified to present only an external radiation hazard and only a remote possibility for contamination.
16. n.o.s. means "not otherwise specified" - 171.8
17. 171.8
18. 173.415 (a)
19. The technical bases for determination of Type A quantities are found in IAEA Safety Series No.7 Explanatory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (1985 Edition); Available from UN Publication, New York, NY.
20. 173.403 - Type B(), Type B(U) and Type B(M) definitions
21. 173.421 - Requirements for limited quantity of material
22. The nonfixed contamination on the external surface of the package does not exceed the limits of 173.443.
23. 173.422
24. 172.403(c) - Requirements for label categories
25. 173.403 - Transport Index (TI) defined
26. 177.842 - Maximum TI per vehicle and required minimum separation distance
27. Packages that exceed 200 mrem/hr at the surface or a TI greater than 10 may be transported in an exclusive-use vehicle. Transport controls are found in 173.441(b).
28. For the White-I category: If the measured TI is not greater than 0.05, the value may be considered 0 (172.403(c).
29. 173.441(b)
30. 173.441 (a)
31. An overpack is an enclosure of two or more packages used for ease of handling. Requirements for marking are found in 173.25 and for labeling in 173.448(g).
32. The US DOT restricts use of passenger-carrying aircraft to transport packages or overpacks with a TI of not more than 3.0; and the material is certified as intended for use in, or incident to research, medical diagnosis or treatment (173.448 (e), (f)).
33. Orientation labels are commercially available in compliance with the required specification of 172.312 .
34. 171.8
35. See note to 171.15
36. 178.350 (b)
37. 171.202
38. 172.203(c)
39. Do not use pre-calibrated activity. The quantity is always at the day of offering to the carrier.
40. The Guidebook is commercially available from supplies such as J.J. Keller or Label Master.

QUESTIONS

1. The Federal agency given authority to regulate the transportation of radioactive material in commerce is
 - a. DOT.
 - b. NRC.
 - c. EPA.
 - d. OSHA.

2. Training in the hazardous material regulations is required of persons who
 - a. ship a radiopharmaceutical.
 - b. deliver a radiopharmaceutical.
 - c. package for shipment a radiopharmaceutical.
 - d. all of the above

3. The regulations governing the shipping and transportation of radiopharmaceuticals are found in
 - a. 10 CFR.
 - b. 21 CFR.
 - c. 40 CFR.
 - d. 49 CFR.

4. Requirements for shipping papers, labels, markings, and placards are found in
 - a. Part 171.
 - b. Part 172.
 - c. Part 173.
 - d. Part 177.

5. The proper shipping name for the radiopharmaceutical Thallium- 201 in a Type A package is
 - a. Thallium, n.o.s.
 - b. Radiopharmaceutical, n.o.s.
 - c. Radioactive Material, n.o.s.
 - d. Radionuclide, n.o.s.

6. The Transport Index of a package with a radiation level of 0.92 mrem/hr at one meter from the package surface is
 - a. 0.
 - b. 0.9.
 - c. 0.92.
 - d. 1.0.

7. A package with a maximum radiation level of 70 mrem/hr at the surface and a TI of 0.8 must be labeled
 - a. Radioactive Yellow-II with TI of 0.8.
 - b. Radioactive Yellow-II with a TI of 1.0.
 - c. Radioactive Yellow-III with a TI of 0.8.
 - d. Radioactive Yellow-III with a TI of 70.

8. The maximum permitted radiation level for a package transported in a non-exclusive use vehicle is
 - a. 200 mrem/hr at the surface.
 - b. 10.0 mrem/hr at 1 meter.
 - c. both a and b.
 - d. neither a or b are correct

9. The basic shipping description for a package containing a hazardous substance radionuclide is
- Radioactive material n.o.s. 7 UN 2982 RQ.
 - Radioactive material n.o.s. (RQ) 7 UN 2982.
 - HM Radioactive material n.o.s. 7 UN 2982.
 - HS Radioactive material n.o.s. 7 UN 2982.
10. A transport vehicle must be placarded with four "Radioactive" placards when
- the placarding of vehicles transporting radiopharmaceutical is not required.
 - transporting any quantity of radioactive material other than excepted packages containing a limited quantity of material.
 - transporting one or more packages labeled Yellow-III.
 - transporting more than 50 TI.
11. What is the maximum quantity of Thallium 201, in solution, that may be shipped as a limited quantity? The A_2 value for TI-201 is 270 Curies.
- 270 millicuries
 - 27 millicuries
 - 2.7 millicuries
 - 0.27 millicuries
12. The A_2 quantity for I-129 is unlimited. The RQ value is 1 millicurie. The maximum quantity of I-29 permitted in an excepted package containing a limited quantity of material is
- 1 millicurie.
 - 10^{-3} (solids) and 10^{-4} (liquids).
 - unlimited.
 - not permitted in an excepted package.
13. A shipper of a Type A packaging must have on file a complete package performance safety analysis for a time period of _____ after the latest shipment.
- 90 days
 - one year
 - 3 years
 - 10 years
14. Each Type A package containing a Radiopharmaceutical must be marked with
- the radionuclide in the package.
 - Class 7.
 - UN 2982.
 - the transportation emergency telephone number.
15. An authorized specification marking, for a Type A packaging is
- a minimum of 0.5 inches in size.
 - USA DOT 7A Type A.
 - Radioactive material.
 - all of the above.
16. The activity recorded on a radioactive label must be
- in Becquerel units.
 - the quantity at the time of offering.
 - in curie, millicurie or microcurie units.
 - both a and b.

17. For a Radioactive White-I Label, the TI is
 - a. 0 for less than 0.5.
 - b. 0 if not greater than 0.05.
 - c. both a and b.
 - d. neither a or b.

18. The maximum TI for a Radioactive Yellow-II Label is
 - a. 0.
 - b. 1.0.
 - c. 3.0.
 - d. 10.

19. Shipping papers must be kept on file for a period of not less than
 - a. 90 days.
 - b. 1 year.
 - c. 3 years.
 - d. Retention of shipping papers is not required.

20. The vehicle operator must ensure that packages are
 - a. prevented from movement in the vehicle during normal transportation.
 - b. in proper condition for transport.
 - c. loaded in accordance with the minimum separation distance.
 - d. all of the above.

21. The operator of a vehicle must have a Commercial Drivers License with a hazardous material endorsement when transporting
 - a. one or more package labeled Radioactive Yellow-III.
 - b. more than 10 TI.
 - c. any quantity of radioactive material.
 - d. not applicable to radiopharmaceutical shipments.

22. The vehicle operator must keep shipping papers
 - a. visible and within reach when fasten with the lab belt.
 - b. in a protected location such as in the glove compartment.
 - c. with the package.
 - d. in any convenient location.

23. The transportation emergency telephone number must be on the
 - a. package.
 - b. shipping paper.
 - c. placard.
 - d. both a and b.

24. The emergency telephone must be
 - a. monitored by a person knowledgeable of the hazards and incident mitigation.
 - b. monitored 24 hours a day, seven days a week while the material is in transportation.
 - c. clearly visible and identified on the shipping papers.
 - d. all of the above.

25. Emergency response information is not required for
 - a. an excepted package containing a limited quantity of material
 - b. radiopharmaceuticals
 - c. material transported in private transportation
 - d. all of the above