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Update on Department of Transportation Regulations

Continuing Education for Nuclear Pharmacists
and Nuclear Medicine Professionals

By

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UPDATE ON DEPARTMENT OF TRANSPORTATION REGULATION

STATEMENT OF OBJECTIVES

The purpose of this lesson is to provide insight into the DOT rules/regulations (historic and on-going). Further, to express the significance of proper interpretation thereof in all aspects of the transportation cycle.

Upon successful completion of this lesson, the reader should be able to:

1. Describe the DOT regulations pertinent to nuclear pharmacy practice, historic and new.
2. Apply the DOT regulations appropriately.
3. Evaluate inspection guidance for compliance.
4. Discuss key hazard communication concepts for Class 7.

COURSE OUTLINE

UPDATE ON DEPARTMENT OF TRANSPORTATION REGULATIONS

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INTRODUCTION

The transportation of radioactive materials has occurred in the United States for more than fifty years.[1] Radioactive materials (RAM) are contained within three million of the 100 million hazardous materials packages shipped annually.[2] This translates into one out of every 33 packages shipped each year. Ensuring that the transportation of radioactive material packages is performed safely is vital to the workers involved, the general public, and the environment. Regulations are in place to help accomplish this task.

RESPONSIBILITY OF AGENCIES

The Nuclear Regulatory Commission (NRC) and the Department of Transportation (DOT) have an inter-relationship of authority for the regulations pertaining to the transportation of RAM. The NRC licenses the organizations which ship and receive radioactive materials and establishes the requirements for design and manufacture of packages for larger quantities of RAM. The NRC regulations state that no licensee shall transport licensed material unless in compliance with the DOT regulations in 49 CFR parts 170-189.[3] If DOT regulations are followed, a licensee is exempt from NRC packaging and transportation requirements so long as the package is approved for normal conditions of transport (e.g. Type A package).

The DOT was created under the DOT Act of 1966.[4] The DOT has regulatory responsibility for safety in transportation of all hazardous materials, including radioactive materials.[4] The DOT sets the standards for labeling of radioactive shipments, establishes shipping categories and establishes the criteria for packages used for smaller quantities of radioactive materials. Typically, these small quantity packages are those containing RAM for medical use.

REGULATIONS AND HISTORICAL LEGISLATION

It is important to know who is responsible for the regulations that affect the everyday work-life in nuclear pharmacies. It is equally important to know where the regulations are found. Further, it is important to know the historical legislation as a basis for understanding any new pertinent legislation that is on the horizon.

The Code of Federal Regulations (CFR) codifies the permanent and general rules by the agencies and executive departments of the federal government. It is updated by issues of the *Federal Register*. The CFR is divided into 50 titles which represent areas subject to Federal regulation. Each volume is updated once each calendar year and is issued on a quarterly basis. Table 1 shows the breakdown of the date of each title as it is issued.

Table 1

CFR Titles and corresponding date of annual update	
CFR Titles	**Date Updated Annually**
1 – 16	January 1st
17 – 27	April 1st
28 – 41	July 1st
42 – 50	October 1st

Each title is divided into chapters which typically bear the name of the issuing agency. Each chapter is further divided into subchapters and then parts. The parts cover specific regulatory areas. If parts are large, they may be subdivided into subparts. All the parts are organized in sections and most of the citations are provided at the section level. Figure 1 shows the breakdown of the divisions of the CFR.

Figure 1: Schematic of the divisions of the CFR

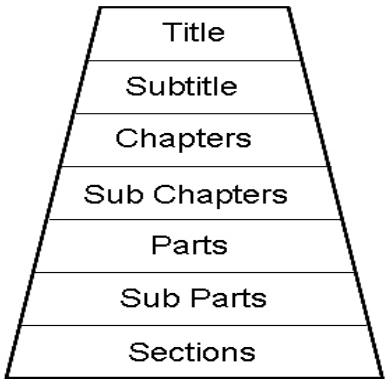


Fig. 2: Title 10 CFR - Energy

There are only 50 titles and there are hundreds of sections. The regulations of the NRC are in Title 10, Energy, of the Code of Federal Regulations. The cover of the printed book is shown in Figure 2. NRC regulations pertaining to transportation are found in Part 71.[5] Figure 3 shows the breakdown of topics under Part 71.[5]

Figure 3 - 10 CFR Part 71

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subpart A—General Provisions

Sec.
71.0 Purpose and scope.
71.1 Communications and records.
71.2 Interpretations.
71.3 Requirement for license.
71.4 Definitions.
71.5 Transportation of licensed material.
71.6 Information collection requirements: OMB approval.
71.7 Completeness and accuracy of information.
71.8 Deliberate misconduct.
71.9 Employee protection.
71.10 Public inspection of application.
71.11 [Reserved]

Subpart B—Exemptions

71.12 Specific exemptions.
71.13 Exemption of physicians.
71.14 Exemption for low-level materials.
71.15 Exemption from classification as fissile material.
71.16 [Reserved]

Subpart C—General Licenses

71.17 General license: NRC-approved package.
71.18 [Reserved]
71.19 Previously approved package.
71.20 General license: DOT specification container.
71.21 General license: Use of foreign approved package.
71.22 General license: Fissile material.
71.23 General license: Plutonium-beryllium special form material.
71.24–71.25 [Reserved]

Subpart D—Application for Package Approval

71.31 Contents of application.
71.33 Package description.
71.35 Package evaluation.
71.37 Quality assurance.
71.38 Renewal of a certificate of compliance or quality assurance program approval.
71.39 Requirement for additional information.

Subpart E—Package Approval Standards

71.41 Demonstration of compliance.
71.43 General standards for all packages.
71.45 Lifting and tie-down standards for all packages.
71.47 External radiation standards for all packages.
71.51 Additional requirements for Type B packages.
71.53 [Reserved]
71.55 General requirements for fissile material packages.
71.57 [Reserved]
71.59 Standards for arrays of fissile material packages.
71.75 Qualification of special form radioactive material.
71.77 Qualification of LSA-III Material.

Subpart G—Operating Controls and Procedures

71.81 Applicability of operating controls and procedures.
71.83 Assumptions as to unknown properties.
71.85 Preliminary determinations.
71.87 Routine determinations.
71.88 Air transport of plutonium.
71.89 Opening instructions.
71.91 Records.
71.93 Inspection and tests.
71.95 Reports.
71.97 Advance notification of shipment of irradiated reactor fuel and nuclear waste.
71.99 Violations.
71.100 Criminal penalties.

Subpart H—Quality Assurance

71.101 Quality assurance requirements.
71.103 Quality assurance organization.
71.105 Quality assurance program.
71.107 Package design control.
71.109 Procurement document control.
71.111 Instructions, procedures, and drawings.
71.113 Document control.
71.115 Control of purchased material, equipment, and services.
71.117 Identification and control of materials, parts, and components.
71.119 Control of special processes.
71.121 Internal inspection.
71.123 Test control.
71.125 Control of measuring and test equipment.
71.127 Handling, storage, and shipping control.
71.129 Inspection, test, and operating status.
71.131 Nonconforming materials, parts, or components.
71.133 Corrective action.
71.135 Quality assurance records.
71.137 Audits.

The regulations of the DOT are in Title 49, Transportation, of the Code of Federal Regulations. Figure 4 displays the printed front cover of the book. The DOT regulations are divided into two subtitles, A and B. Figure 5 shows an excerpt from the title page of subtitle B.[6]

Fig. 4: Title 49, Transportation

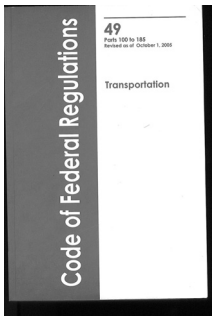


Fig. 5: Excerpt of Subtitle B of 49 CFR 6

Title 49—Transportation

(This book contains parts 100 to 185)

SUBTITLE B—OTHER REGULATIONS RELATING TO TRANSPORTATION

Part

CHAPTER I—Pipeline and Hazardous Materials Safety Administration, Department of Transportation 105

Chapter I under subtitle B is entitled Pipeline and Hazardous Materials Safety Administration (PHMSA).[6] This Administration is responsible for transportation of hazardous materials. It was

formerly named the Research and Special Programs Administration (RSPA) until October 1, 2005. Hazardous materials information is found under subchapters A through C of this chapter for PHMSA as shown in Figure 6.[6]

Hazardous materials program definitions, rulemaking and procedures are found in Parts 105, 106 and 107, respectively. HMR is defined as the hazardous materials regulations in parts 171 through 180.[7] The HMR parts of Title 49 applicable to radioactive materials are 171, 172, 173, 175, 177 and 178.

Figure 6 - 49 CFR § 173.436

Title 49—Transportation

(This index contains parts 100 to 185)

Subtitle B—Other Regulations Relating to Transportation

CHAPTER 1—PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

Part	
105	Hazardous Materials Program definition and general procedures
106	Rulemaking procedure
107	Hazardous materials program procedures
110	Hazardous materials public sector training and planning grants
130	Oil spill prevention and responsible plans
171	General information, regulations and definitions
172	Hazardous materials table, special provisions, hazardous materials, communications, emergency response information and training requirements
173	Shippers—general requirements for shipments and packaging
174	Carriage by rail
175	Carriage by aircraft
176	Carriage by vessel
177	Carriage by public highway
178	specifications for packagings
179	Specifications for tank cars
180	Continuing qualifications and maintenance of packagings
181-185	[Reserved]

Part 171 covers general information, regulations and definitions. It contains the purpose and scope of the regulations, definitions and abbreviations of hazardous materials and conversion factors for SI units. Further, it describes the DOT reporting requirements for incidents, accidents, and releases of hazardous substances.

Part 172 covers the hazardous materials table, special provisions, hazardous materials communications, emergency response information and training requirements. Its subparts contain the topics of shipping papers, marking, labeling, placarding and security plans.

Part 173 covers general requirements for shipments and packaging. This part is organized according to nine hazard classes. Radioactive materials are in hazard class number seven.

Part 175 covers carriage by aircraft in commerce information. It distinguishes between passenger-carrying and cargo-only aircraft.

Part 177 covers carriage by public highway and applies to all highway carriers. Its subparts highlight shipping paper placement as well as loading and unloading packages.

Part 178 covers specifications for packaging. General packaging information for Type A packages used with radioactive materials is covered on its own.

Table 2 highlights specific DOT regulations applicable to some of the aforementioned parts of CFR 49 and where particular topics can be found. For example, training topics can be cross-referenced to parts 172.700, 172.702 and 172.703.

Table 2

DOT Specific Regulations For Nuclear Pharmacy Practice[7]	
Requirements	**DOT references**
Civil Penalties – Guidelines	107.339, Subpart D, Appendix A
Reporting: Incidents/Accidents	171.15 Earliest Report 171.16 Detailed Report 172.600, 602, 604: Emergency Response
HM Table	172.101
Reportable Quantities	172.101, Appendix A, Table 2
Shipping Papers Shipper Certification	172, Subpart C 172.200, 201, 202, 203 172.204
Marking	172, Subpart D 172.300, 301, 304, 310, 312, 334
Labeling	172, Subpart E 172.400, 401, 402, 403, 404, 406, 407, 436, 438, 440, 448, 450
Placarding	172, Subpart F 172.500, 519, 556
Training	172, Subpart H 172.700, 702, 704
Shippers requirements for shipments/packages HM classifications Type A packages Excepted packages for Limited Quantity Multiple hazards A_1 and A_2 values Radiation level limits Contamination level limits General transportation requirements	173, Subpart 1 173.2, 403 173.410, 412, 415, 431, 433, 465, 466 173.421, 422, 425, 428 173.423 173.433, 435 173.441 173.448 173.475
Carriers – public highway Driver training Shipping papers Loading/blocking and bracing Vehicle TI limit/distances	177 177.816 177.817 177.834 177.842
Specifications for packages Package marking RAM packages	178 178.2, 178.3 Subpart K

While the DOT Act of 1966 was the keystone legislation that established the Department of Transportation, it is not the only transportation legislation. Through the years, there have been many changes and adaptations to the regulations in the United States. All these have been recorded in the *Federal Register*. Any new regulations are issued in dockets which are referred to as HM-XXX. Additionally, each regulatory action is assigned a regulation identifier number or RIN. The RIN is listed in the Unified Agenda of Federal Regulations. This agenda is published each year in April and October. The RIN along with the HM number and the document headings can be used to cross-reference regulatory actions.

The DOT is the primary regulator of hazardous material transportation. The Hazardous Materials Transportation Act (HMTA) of 1974 gave the secretary of transportation broad authority to declare and enforce the regulations.[8] This was done to "protect the nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce." This regulation was enacted to govern packaging, marking, and labeling of hazardous materials (Hazmats), transportation procedures and specifications for vehicles, aircraft, rail and vessels carrying hazardous materials.

The Hazardous Materials Transportation Uniform Safety Act of 1990 amended the HMTA with revision HM-181, which addressed shipping papers, training requirements, motor carrier permits and other minor issues. The goal of HM-181 was to make DOT regulations compliant with international regulations in order to ensure safe transportation of hazardous materials.[9] This comprehensive revision to the DOT regulations was based on United Nations (UN) recommendations. HM-181 was first issued on December 21, 1990. It had notable changes in packaging specifications, including the closures used and the types of tests performed (e.g. drop test). Radioactive materials packages have always been required to meet performance test criteria.

The next revision was HM-169A. This legislation brought substantial changes to HM-181. It was published by the NRC and DOT on September 28, 1995[10] and was phased into effect over the next two years. The goal of HM-169A was harmonization with international standards, in particular the International Atomic Energy Agency (IAEA) regulations on the transportation of RAM outlined in the 1985 revision of Safety Series No. 6. This legislation, made effective April 1, 1997, mandated the use of SI units for domestic and international shipments, made modifications to type package certification, and expanded the A_1 and A_2 values approval for derived values. The mandate required listing SI units

first, or optionally listing SI units followed by traditional units in parentheses. This revision is still in effect today.

Alignment with the international regulations remains a primary goal of the DOT regulations today. Since its initial publication of regulations in 1961, the IAEA regulations have been recommended by the UN to its member states as the basis of their regulations governing transportation. Member states of the UN include 192 countries worldwide. Most member states have since adopted the IAEA regulations as the basis of their national regulations. In the case of the 1973 and 1985 IAEA major updates to Safety Series No. 6, the DOT brought the HMR requirements relating to the transportation of RAM into harmonization in 1983 and 1995, respectively. Further, the DOT coordinated these revisions with the NRC which concurrently updated 10 CFR 71.

ON-GOING LEGISLATION

Remaining compatible with the majority of other industrialized nations in the world is an on-going process for the United States and its DOT regulations. With the two past major updates to the IAEA regulations being incorporated worldwide, the IAEA published its most recent major revision in 1996. The IAEA entitled its publication "IAEA Safety Standards Series: Regulations for the Safe Transport of Radioactive Material, " 1996 Edition. No. TS-R-1. It is more commonly referred to as ST-1. While this is not the only driver of change for DOT rules and regulations, it does have a major effect on update efforts.

HM-230

The first advance notice of proposed rulemaking by the DOT regarding ST-1 was issued in the *Federal Register* in late December of 1999.[11] The DOT docket for this rulemaking is HM-230. This legislation covered a wide variety of topics including the following: updates to proper shipping names and UN numbers, changing the definition of radioactive materials, requiring packages be marked with UN numbers (e.g. limited quantities), package type and country of origin, updates to A_1 and A_2 values and updates to the definitions of TI and contamination.

HM-230 became effective on July 1, 2001. The DOT, as part of the harmonization process with the IAEA, adopted the rule change at that time but only for air transportation. Phasing in the rule changes has been a common practice by the DOT but this instance led to a unique situation with proper shipping names and UN numbers.

The proper shipping name for air shipments was updated as follows:

RADIOACTIVE MATERIAL, TYPE A PACKAGE UN2915

However, the proper shipping name for ground, either highway or rail, continued to be the following:

RADIOACTIVE MATERIAL, N.O.S., UN2982

Many radioactive material packages are shipped from manufacturers by aircraft and then transferred to motor carriage for additional transportation to their final site of use. Instead of requiring shippers to change the proper shipping name in the middle of the route, shippers were allowed to adopt the new proper shipping name for aircraft. This held true only when the shippers updated several requirements related to the proper shipping name including training, Quality Assurance Program and updating their emergency procedures.

The proper shipping name, Radioactive Material, N.O.S., UN2982, was deleted from the DOT regulations on October 1, 2004. Thus, the proper shipping name and UN number used only for aircraft is now used for all transportation vehicles.

There were other significant changes to HM-230 in the final rule published January 26, 2004 that became effective on October 1, 2004.[12] These changes affect the transportation of radioactive materials in nuclear pharmacy practice and are as follows:

The definition of radioactive materials was updated. Prior to this update, a material was considered radioactive for transportation purposes if it had a specific activity threshold of 70 Bq/g (0.0002 microCuries/g). This definition was replaced with nuclide-specific activity concentration thresholds for material to be considered hazard Class 7. Further, material must also exceed the consignment activity thresholds to be considered hazard Class 7. Figure 7 shows some radionuclides with their associated activity concentration thresholds.[7]

Thus only when both the activity concentration and the consignment activity are greater than the exemption values is the material considered to be radioactive and regulated as hazard Class 7 for the purposes of transportation.

Figure 7: Excerpts from Table 49 CFR 173.436

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Bk-247	Berkelium (97)	1.0	2.7×10^{-11}	1.0×10^{4}	2.7×10^{-7}
Bk-249		1.0×10^{3}	2.7×10^{-8}	1.0×10^{6}	2.7×10^{-5}
Br-76	Bromine (35)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Br-77		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Br-82		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
C-11	Carbon (6)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
C-14		1.0×10^{4}	2.7×10^{-7}	1.0×10^{7}	2.7×10^{-4}
Ca-41	Calcium (20)	1.0×10^{5}	2.7×10^{-6}	1.0×10^{7}	2.7×10^{-4}
Ca-45		1.0×10^{4}	2.7×10^{-7}	1.0×10^{7}	2.7×10^{-4}
Ca-47		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Cd-109	Cadmium (48)	1.0×10^{4}	2.7×10^{-7}	1.0×10^{6}	2.7×10^{-5}
Cd-113m		1.0×10^{3}	2.7×10^{-8}	1.0×10^{6}	2.7×10^{-5}
Cd-115		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Cd-115m		1.0×10^{3}	2.7×10^{-8}	1.0×10^{6}	2.7×10^{-5}
Ce-139	Cerium (58)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Ce-141		1.0×10^{2}	2.7×10^{-9}	1.0×10^{7}	2.7×10^{-4}
Ce-143		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Ce-144 (b)		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Cf-248	Californium (98)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{4}	2.7×10^{-7}
Cf-249		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Cf-250		1.0×10^{1}	2.7×10^{-10}	1.0×10^{4}	2.7×10^{-7}
Cf-251		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Cf-252		1.0×10^{1}	2.7×10^{-10}	1.0×10^{4}	2.7×10^{-7}
Cf-253		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Cf-254		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Cl-36	Chlorine (17)	1.0×10^{4}	2.7×10^{-7}	1.0×10^{6}	2.7×10^{-5}
Cl-38		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Cm-240	Curium (96)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Cm-241		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Cm-242		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Cm-243		1.0	2.7×10^{-11}	1.0×10^{4}	2.7×10^{-7}
Cm-244		1.0×10^{1}	2.7×10^{-10}	1.0×10^{4}	2.7×10^{-7}
Cm-245		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Cm-246		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Cm-247		1.0	2.7×10^{-11}	1.0×10^{4}	2.7×10^{-7}
Cm-248		1.0	2.7×10^{-11}	1.0×10^{3}	2.7×10^{-8}
Co-55	Cobalt (27)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Co-56		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Co-57		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Co-58		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Fe-55		1.0×10^{4}	2.7×10^{-7}	1.0×10^{6}	2.7×10^{-5}
Fe-59		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Fe-60		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Ga-67	Gallium (31)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Ga-68		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Ga-72		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Gd-145	Gadolinium (64)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Gd-148		1.0×10^{1}	2.7×10^{-10}	1.0×10^{4}	2.7×10^{-7}
Gd-153		1.0×10^{2}	2.7×10^{-9}	1.0×10^{7}	2.7×10^{-4}
Gd-159		1.0×10^{3}	2.7×10^{-8}	1.0×10^{6}	2.7×10^{-5}
Ge-68	Germanium (32)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Ge-71		1.0×10^{4}	2.7×10^{-7}	1.0×10^{8}	2.7×10^{-3}
Ge-77		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
Hf-172	Hafnium (72)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Hf-175		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Hf-181		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Hf-182		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Hg-194	Mercury (80)	1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
Hg-195m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Hg-197		1.0×10^{2}	2.7×10^{-9}	1.0×10^{7}	2.7×10^{-4}
Hg-197m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Hg-203		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
Ho-166	Holmium (67)	1.0×10^{3}	2.7×10^{-8}	1.0×10^{5}	2.7×10^{-6}
Ho-166m		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
I-123	Iodine (53)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{7}	2.7×10^{-4}
I-124		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
I-125		1.0×10^{3}	2.7×10^{-8}	1.0×10^{6}	2.7×10^{-5}
I-126		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
I-129		1.0×10^{2}	2.7×10^{-9}	1.0×10^{5}	2.7×10^{-6}
I-131		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
I-132		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
I-133		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
I-134		1.0×10^{1}	2.7×10^{-10}	1.0×10^{5}	2.7×10^{-6}
I-135		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}
In-111	Indium (49)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
In-113m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
In-114m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
In-115m		1.0×10^{2}	2.7×10^{-9}	1.0×10^{6}	2.7×10^{-5}
Ir-189	Iridium (77)	1.0×10^{2}	2.7×10^{-9}	1.0×10^{7}	2.7×10^{-4}
Ir-190		1.0×10^{1}	2.7×10^{-10}	1.0×10^{6}	2.7×10^{-5}

The A_1 and A_2 values in HM-230 were calculated using the updated Q system.[7] The Q system used improved assumptions, updated dosimetric models, and new biokinetic data. Figure 8 depicts a partial list of the radionuclides along with their updated Q system derived values.[7] Two exceptions to this update were granted for domestic shipments. They were for Mo-99 and Cf-252. The domestic exceptions were granted because changing the values would increase exposure to workers and significantly increase cost of shipments. Mo-99 retained its A_2 value of 0.74 TBq (20 Ci). Cf-252 kept its A_1 value of 0.1 TBq (2.7 Ci) and A_2 value of 0.001 TBq (0.027 Ci). In conjunction with the changes in A_1 and A_2 values, the limited

Figure 8: Excerpt from Table 49 CFR 173.4357

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	Specific activity (TBq/g)	Specific activity (Ci/g)
Tl-201		1.0×10^{1}	2.7×10^{2}	4.0	1.1×10^{2}	7.9×10^{3}	2.1×10^{5}
Tl-202		2.0	5.4×10^{1}	2.0	5.4×10^{1}	2.0×10^{3}	5.3×10^{4}
Tl-204		1.0×10^{1}	2.7×10^{2}	7.0×10^{-1}	1.9×10^{1}	1.7×10^{1}	4.6×10^{2}
Tm-167	Thulium (69)	7.0	1.9×10^{2}	8.0×10^{-1}	2.2×10^{1}	3.1×10^{3}	8.5×10^{4}
Tm-170		3.0	8.1×10^{1}	6.0×10^{-1}	1.6×10^{1}	2.2×10^{2}	6.0×10^{3}
Tm-171		4.0×10^{1}	1.1×10^{3}	4.0×10^{1}	1.1×10^{3}	4.0×10^{1}	1.1×10^{3}
U-230 (fast lung absorption) (a)(d).	Uranium (92)	4.0×10^{1}	1.1×10^{3}	1.0×10^{-1}	2.7	1.0×10^{3}	2.7×10^{4}
U-230 (medium lung absorption) (a)(e).		4.0×10^{1}	1.1×10^{3}	4.0×10^{-3}	1.1×10^{-1}	1.0×10^{3}	2.7×10^{4}
U-230 (slow lung absorption) (a)(f).		3.0×10^{1}	8.1×10^{2}	3.0×10^{-3}	8.1×10^{-2}	1.0×10^{3}	2.7×10^{4}
U-232 (fast lung absorption) (d).		4.0×10^{1}	1.1×10^{3}	1.0×10^{-2}	2.7×10^{-1}	8.3×10^{-1}	2.2x10¹
U-232 (medium lung absorption) (e).		4.0×10^{1}	1.1×10^{3}	7.0×10^{-3}	1.9×10^{-1}	8.3×10^{-1}	2.2x10¹
U-232 (slow lung absorption) (f).		1.0×10^{1}	2.7×10^{2}	1.0×10^{-3}	2.7×10^{-2}	8.3×10^{-1}	2.2x10¹
U-233 (fast lung absorption) (d).		4.0×10^{1}	1.1×10^{3}	9.0×10^{-2}	2.4	3.6×10^{-4}	9.7×10^{-3}
U-233 (medium lung absorption) (e).		4.0×10^{1}	1.1×10^{3}	2.0×10^{-2}	5.4×10^{-1}	3.6×10^{-4}	9.7×10^{-3}
U-233 (slow lung absorption) (f).		4.0×10^{1}	1.1×10^{3}	6.0×10^{-3}	1.6×10^{-1}	3.6×10^{-4}	9.7×10^{-3}
U-234 (fast lung absorption) (d).		4.0×10^{1}	1.1×10^{3}	9.0×10^{-2}	2.4	2.3×10^{-4}	6.2×10^{-3}
U-234 (medium lung absorption) (e).		4.0×10^{1}	1.1×10^{3}	2.0×10^{-2}	5.4×10^{-1}	2.3×10^{-4}	6.2×10^{-3}
U-234 (slow lung absorption) (f).		4.0×10^{1}	1.1×10^{3}	6.0×10^{-3}	1.6×10^{-1}	2.3×10^{-4}	6.2×10^{-3}
U-235 (all lung absorption types) (a),(d),(e),(f).		Unlimited	Unlimited	Unlimited	Unlimited	8.0×10^{-8}	2.2x10⁻⁶
U-236 (fast lung absorption) (d).		Unlimited	Unlimited	Unlimited	Unlimited	2.4×10^{-6}	6.5×10^{-5}
U-236 (medium lung absorption) (e).		4.0×10^{1}	1.1×10^{3}	2.0×10^{-2}	5.4×10^{-1}	2.4×10^{-6}	6.5×10^{-5}
U-236 (slow lung absorption) (f).		4.0×10^{1}	1.1×10^{3}	6.0×10^{-3}	1.6×10^{-1}	2.4×10^{-6}	6.5×10^{-5}
U-238 (all lung absorption types) (d),(e),(f).		Unlimited	Unlimited	Unlimited	Unlimited	1.2×10^{-8}	3.4×10^{-7}
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	2.6×10^{-8}	7.1×10^{-7}
U (enriched to 20% or less)(g).		Unlimited	Unlimited	Unlimited	Unlimited	see § 173.434	see § 173.4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	see § 173.434	see § 173.4
V-48	Vanadium (23)	4.0×10^{-1}	1.1×10^{1}	4.0×10^{-1}	1.1×10^{1}	6.3×10^{3}	1.7×10^{5}
V-49		4.0×10^{1}	1.1×10^{3}	4.0×10^{1}	1.1×10^{3}	3.0×10^{2}	8.1×10^{3}
W-178 (a)	Tungsten (74)	9.0	2.4×10^{2}	5.0	1.4×10^{2}	1.3×10^{3}	3.4×10^{4}
W-181		3.0×10^{1}	8.1×10^{2}	3.0×10^{1}	8.1×10^{2}	2.2×10^{2}	6.0×10^{3}
W-185		4.0×10^{1}	1.1×10^{3}	8.0×10^{-1}	2.2×10^{1}	3.5×10^{2}	9.4×10^{3}
W-187		2.0	5.4×10^{1}	6.0×10^{-1}	1.6×10^{1}	2.6×10^{4}	7.0×10^{5}
W-188 (a)		4.0×10^{-1}	1.1×10^{1}	3.0×10^{-1}	8.1	3.7×10^{2}	1.0×10^{4}
Xe-122 (a)	Xenon (54)	4.0×10^{-1}	1.1×10^{1}	4.0×10^{-1}	1.1×10^{1}	4.8×10^{4}	1.3×10^{6}
Xe-123		2.0	5.4×10^{1}	7.0×10^{-1}	1.9×10^{1}	4.4×10^{5}	1.2×10^{7}
Xe-127		4.0	1.1×10^{2}	2.0	5.4×10^{1}	1.0×10^{3}	2.8×10^{4}

quantity activity limits for special and normal form also changed. However the calculation method remained intact. For example, normal form limited quantity activity limits are as follows: solids and gases 1/1,000 of the A_2 value and liquids 1/10,000 of the A_2 value.[7]

Table 3 depicts the old and new A_2 values for some radionuclides and their corresponding limited quantity amounts.[13]

Table 3

A_2 Values and Limited Quantity Amounts[7,13]						
Radionuclide	**Old A_2 Value (TBq)**	**Old A_2 Value (Ci)**	**Old Limited Quantity Amount (Ci)**	**New A_2 Value (TBq)**	**New A_2 Value (Ci)**	**New Limited Quantity Amount (Ci)**
Ba-133 (solid)	3	81.1	0.0811	3	81	0.081
Co-57 (solid)	8	216	0.216	10	270	0.270
Co-57 (liquid)	8	216	0.0216	10	270	0.027
Cr-51 (liquid)	30	811	0.0811	30	810	0.081
F-18 (liquid)	0.5	13.5	0.00135	0.6	16	0.0016
Ga-67 (liquid)	6	162	0.0162	3	81	0.0081
I-123 (liquid)	6	162	0.0162	3	81	0.0081
I-123 (solid)	6	162	0.162	3	81	0.081
I-125 (liquid)	2	54.1	0.00541	3	81	0.0081
I-131 (liquid)	0.5	13.5	0.00135	0.7	19	0.0019
I-131 (solid)	0.5	13.5	0.0135	0.7	19	0.019
In-111 (liquid)	2	54.1	0.00541	3	81	0.0081
P-32 (liquid)	0.3	8.11	0.000811	0.5	14	0.0014
Tc-99m(liquid)	8	216	0.0216	4	110	0.011
Tl-201 (liquid)	10	270	0.0270	4	110	0.011
Y-90 (liquid)	0.2	5.41	0.000541	0.3	8.1	0.00081

Several changes were adopted which related to packages. UN numbers are now required to be marked on excepted packages (e.g. UN2910 on Limited Quantity and UN2908 on Empty packages).

Additionally, the excepted package certification requirement has been removed. The package type must be marked appropriately. For most nuclear pharmacy shipments this requires marking the package as "Type A". The International Vehicle Registration code for the country of origin must be marked on the package. This translates into marking "USA" on Type A and industrial packages. The wording "Radioactive Material" marking requirement was removed. This was the result of this phrase being redundant since it is now required to be included as part of the proper shipping name.

In radioactive shipments, the transport index (TI) had been defined to serve a dual role. First, regarding radiation hazard. The first roll of the TI was to describe the radiation dose rate at one meter from a RAM package. Second, the TI had been used in the determination a fissile package's

criticality control hazard. For criticality control purposes, TI could be the number obtained by dividing fifty by the allowable number of packages which may be transported together. For fissile packages, the TI was the larger of either the dose rate at one meter or the criticality control number. The criticality control TI was removed from the regulations and, in its place, the Criticality Safety Index (CSI) was introduced for fissile material. This change clarifies the use of TI to solely describe a package's radiation hazard. The TI is the maximum dose rate in mRem/h at 1 meter from the package surface and is rounded up to the nearest tenth. For example, if a dose rate at one meter measures 0.12, the TI is recorded as 0.2. TI is a dimensionless number, thus the units mRem/h are dropped. The transport index is used as the definitive guidance for package and overpack allowance on aircraft and in vehicles. The transport index on any one item cannot exceed 10.0 for cargo aircraft or 3.0 for passenger-carrying aircraft.[7] Further, the TI is prescriptive regarding the minimum separation distance between the radioactive materials and the crew/passengers. Table 4 highlights the required separation distances between packages and people.[7]

Table 4

Excerpts From 49 CFR Part 175.701 Separation Distances For Aircraft[7]	
Transport Index or sum of the TI's on all packages	**Minimum separation distance between people and RAM packages in Centimeters**
0.1 to 1.0	30
1.1 to 2.0	50
2.1 to 3.0	70
3.1 to 4.0	85
4.1 to 5.0	100
5.1 to 6.0	115
6.1 to 7.0	130
7.1 to 8.0	145
8.1 to 9.0	155
9.1 to 10.0	165
14.1 to 15.0	215
18.1 to 20.0	260
20.1 to 25.0	290
25.1 to 30.0	320
35.1 to 40.0	375
40.1 to 50.0	425

As for motor vehicles, the TI also yields definitive guidance on separation distances as described in Table 5.[7] The TI serves an important role in informing people on how to handle radioactive packages correctly.

Table 5

Excerpts From 49 CFR Part 177.842 Separation Distances For Highway Vehicles[7]	
Total Transport Index	**Minimum separation distance in Meters (feet) from dividing partition**
None	0.0 (0)
0.1 to 1.0	0.3 (1)
1.1 to 5.0	0.6 (2)
5.1 to 10.0	0.9 (3)
10.1 to 20.0	1.2 (4)
20.1 to 30.0	1.5 (5)
30.1 to 40.0	1.8 (6)
40.1 to 50.0	2.1 (7)

Contamination is always a concern when handling radioactive materials and this is especially true with the transportation process. The definition of contamination has been changed to include non-fixed and fixed contamination. The proper surface area of a package to wipe is 300 cm^2. The actual efficiency of the instrumentation used to count the wipe may be used or the efficiency can be assumed to be 0.1. Table 6 shows the non-fixed contamination limits for packages.[7] The limits in the table cannot be exceeded at any time in the transportation process (e.g., shipping and receipt of packages).

Table 6

Non-Fixed External Radiation Package Contamination Levels[7]			
Contaminant	**Maximum Permissible Limits**		
	Bq/cm^2	**uCi/cm^2**	**dpm/cm^2**
Beta and Gamma emitters (& low toxicity alpha emitters)	4	10^{-4}	220
All other alpha emitting radionuclides	0.4	10^{-5}	22

The previous maximum permissible limits were 22 dpm/cm^2 for beta and gamma emitters and 2.2 dpm/cm^2 for all other alpha emitting radionuclides.[13] These limits may still be in effect for package receipt in agreement states as they are permitted to be more stringent than the NRC and they are typically behind the NRC in implementation of updates.

HM-223

These revisions pertain to hazardous materials regulations regarding loading, unloading and storage operations. HM-223 had an effective date of June 1, 2005.[13] HM-223 clarifies the applicability of hazardous materials regulations to functions undertaken. Some of the divisions of this rule relate to pre-transportation functions, transportation functions, and functions not subject to the hazardous

materials regulations. There is a clear distinction between these functions and they directly affect the function-specific training components for hazmat employees.

Pre-transportation function is "a function performed by any person that is required to assure the safe transportation of a hazardous material in commerce." Examples of pre-transportation functions include but are not limited to package selection, determination of hazard class, package filling, marking, and labeling, preparation of shipping papers, and provision of emergency information.

Transportation functions include movement, loading/unloading, and storage incidental to movement.

The functions which are not subject to the hazardous materials regulations include: "rail and motor vehicle movements of a hazardous material solely within a contiguous facility where public access is restricted; transportation of a hazardous material in a transport vehicle or conveyance operated by a Federal, State, or local government employee solely for government purposes; transportation of a hazardous material by an individual for non-commercial purposes in a private motor vehicle; and any matter subject to the US postal laws and regulations." These functions which are not subject to the hazardous materials regulations do not apply to nuclear pharmacy practice.

HM-232

This rule pertains to security training requirements for those who offer and transport hazardous materials. It became effective on March 25, 2003[14] and was a direct initiative of the Homeland Security Act of 2002. The goal of this rule change was to enhance the security of hazardous materials while in commerce. This rule mandated that hazmat employees must be provided with security training by their hazmat employers.

The training requirement for hazmat employees is explicit in its details on the new topic of security. The security training must include awareness of security-related issues pertaining to the hazardous materials transportation and methods to enhance security measures. Further, it must include the aspects of recognizing and responding to possible threats to security. If a security plan is required for the hazmat employer (e.g., handles highway-route controlled quantities of hazard Class 7 or shipments require placarding), the hazmat employees must also be trained on the contents of the security plan. Persons who are subject to a security plan were given six months from the effective date of the final rule to develop and implement the plan.

As a result of this rule, the hazardous materials regulations now require hazmat employees to be trained in four specific components. These components are general awareness, function specific, safety, and security. The general awareness component covers the rules and regulations governing the transport of radioactive materials and how to recognize and identify hazards. The function specific component covers topics directly applicable to the functions performed by the employee. The safety component of training ensures that hazmat employees are knowledgeable about emergency response information, accident-prevention and self-protection methods. The security component covers topics such as security awareness and recognizing possible threats.

All new employees must receive initial training within 90 days of employment or a change in job function. Recurrent training for hazmat employees must occur every three years. Final rule HM-232 mandated hazmat employers to train hazmat employees on the new security component at their next scheduled retraining or within the three year cycle of training.[15]

HM-240

This hazardous materials regulation became effective on January 9, 2006.[15] It incorporates statutorily mandated revisions to the hazardous materials regulations. The Hazardous Materials Safety and Security Reauthorization Act of 2005 amended the federal hazardous materials law. This update revises the hazardous materials regulations and the hazmat program and rulemaking procedures to be consistent with the Act. These changes will appear in the next revision of Title 49 CFR dated October 1, 2006. This final rule incorporates changes affecting the transportation of hazardous materials in the realm of nuclear medicine. It updates the definitions of a hazmat employee and hazmat employer as well as revises the shipping paper retention requirements.

Who is a hazmat employee? "A person who is: (a) Employed on a full-time, part-time, or temporary basis by a hazmat employer and who in the course of such full-time, part-time or temporary employment directly affects hazardous materials transportation safety; (b) Self-employed (including an owner-operator of a motor vehicle, vessel, or aircraft) transporting hazardous materials in commerce who in the course of such self-employment directly affects the hazardous materials transportation safety; (c) A railroad signalman; or (d) A railroad maintenance-of-way employee."

What type of functions do hazmat employees undertake during the course of their employment? Individuals who "(a) load, unload, or handle hazardous materials; (b) design, manufacture, fabricate, inspect, mark, maintain, recondition, repair, or test at package, container, or packaging component that

is represented, marked, certified, or sold as qualified for transporting hazardous materials in commerce; (c) prepare hazardous materials for transportation; (d) are responsible for safety of transporting hazardous materials; (e) operate a vehicle used to transport hazardous materials."

Who is a hazmat employer? It can describe a self-employed person (i.e., owner-operator), a person who employs or uses at least one hazmat employee, or an agency, department of the US government, authority of a state, political subdivision of a state or an Indian tribe. To be a hazmat employer, the person themselves or someone they oversee would "(a) transport hazardous materials in commerce; (b) cause hazardous materials to be transported in commerce; or (c) design, manufacture, fabricate, inspect, mark, maintain, recondition, repair or test a package, container, or packaging component that is represented, marked, certified, or sold by that person who as qualified for use in transporting hazardous materials in commerce."

Under Title 49 CFR dated October 1, 2005[7], the retention time for shipping papers was 375 days after the shipment was accepted by the initial carrier. This time applied to the person providing and the person receiving the shipping paper. A copy of the shipping paper or an electronic image thereof was acceptable. The retention time set forth in HM-240 has changed. Shippers are now required to retain a copy of the shipping paper for two years after providing the shipping paper to a carrier.[16] The carrier is required to keep a copy of the shipping paper for one year after the date the shipping paper is received.[15] This rule became effective on January 9, 2006, and any shipments on or after this date will follow the new regulation. Any shipments prior to this date are not subject to the new provision. Both shippers and carriers of hazardous waste must continue to follow the existing rules for retention of shipping papers. A hazardous waste shipping paper must be kept for three years after the material is accepted by the initial carrier.

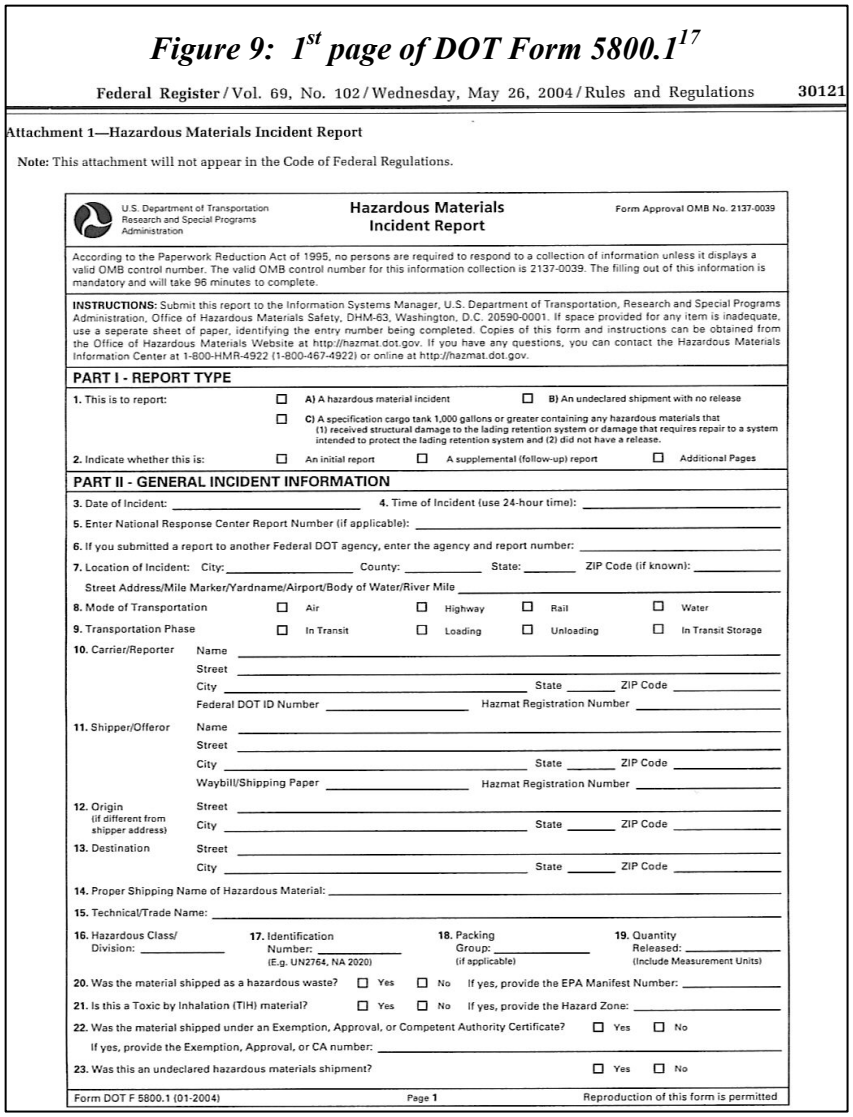
HM-229

The Research and Special Programs Administration (RSPA) published a final rule on December 3, 2003 under Docket HM-229 with an effective date of July 1, 2004.[16] This final rule updated the incident report form and the reporting requirements for incidents. Due to multiple appeals of this final rule, it underwent minor corrections and the updated version became effective on January 1, 2005.[17] The front page of the incident report form DOT F 5800.1 is shown as Figure 9.[18] The necessity to report incidents helps to provide information regarding transportation risks and a better understanding of the consequences and causes of hazmat transportation miscues. Trend analyses will enable closer

scrutiny of the regulations currently in place and identification of areas for increased focus and possible change.

Section 171.15 of the hazardous materials regulations requires an immediate telephonic report of certain types of hazmat incidents as well as a follow-up written report. The term "immediate" in the telephonic reporting requirement translates into as soon as practical but not more than 12 hours after the incident occurrence.[17] Incidents must be reported to the Department of Transportation and to the person in physical possession of the material at the time of the transportation incident.

Figure 9: 1st page of DOT Form 5800.1[17]



Federal Register / Vol. 69, No. 102 / Wednesday, May 26, 2004 / Rules and Regulations 30121

Attachment 1—Hazardous Materials Incident Report

Note: This attachment will not appear in the Code of Federal Regulations.

U.S. Department of Transportation
Research and Special Programs Administration

Hazardous Materials Incident Report

Form Approval OMB No. 2137-0039

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 2137-0039. The filling out of this information is mandatory and will take 96 minutes to complete.

INSTRUCTIONS: Submit this report to the Information Systems Manager, U.S. Department of Transportation, Research and Special Programs Administration, Office of Hazardous Materials Safety, DHM-63, Washington, D.C. 20590-0001. If space provided for any item is inadequate, use a seperate sheet of paper, identifying the entry number being completed. Copies of this form and instructions can be obtained from the Office of Hazardous Materials Website at http://hazmat.dot.gov. If you have any questions, you can contact the Hazardous Materials Information Center at 1-800-HMR-4922 (1-800-467-4922) or online at http://hazmat.dot.gov.

PART I - REPORT TYPE

1. This is to report: ☐ A) A hazardous material incident ☐ B) An undeclared shipment with no release ☐ C) A specification cargo tank 1,000 gallons or greater containing any hazardous materials that (1) received structural damage to the lading retention system or damage that requires repair to a system intended to protect the lading retention system and (2) did not have a release.

2. Indicate whether this is: ☐ An initial report ☐ A supplemental (follow-up) report ☐ Additional Pages

PART II - GENERAL INCIDENT INFORMATION

3. Date of Incident: _____ 4. Time of Incident (use 24-hour time): _____

5. Enter National Response Center Report Number (if applicable): _____

6. If you submitted a report to another Federal DOT agency, enter the agency and report number: _____

7. Location of Incident: City: _____ County: _____ State: _____ ZIP Code (if known): _____

Street Address/Mile Marker/Yardname/Airport/Body of Water/River Mile _____

8. Mode of Transportation ☐ Air ☐ Highway ☐ Rail ☐ Water

9. Transportation Phase ☐ In Transit ☐ Loading ☐ Unloading ☐ In Transit Storage

10. Carrier/Reporter Name _____ Street _____ City _____ State _____ ZIP Code _____ Federal DOT ID Number _____ Hazmat Registration Number _____

11. Shipper/Offeror Name _____ Street _____ City _____ State _____ ZIP Code _____ Waybill/Shipping Paper _____ Hazmat Registration Number _____

12. Origin (if different from shipper address) Street _____ City _____ State _____ ZIP Code _____

13. Destination Street _____ City _____ State _____ ZIP Code _____

14. Proper Shipping Name of Hazardous Material: _____

15. Technical/Trade Name: _____

16. Hazardous Class/Division: _____ 17. Identification Number: _____ (E.g. UN2764, NA 2020) 18. Packing Group: _____ (if applicable) 19. Quantity Released: _____ (Include Measurement Units)

20. Was the material shipped as a hazardous waste? ☐ Yes ☐ No If yes, provide the EPA Manifest Number: _____

21. Is this a Toxic by Inhalation (TIH) material? ☐ Yes ☐ No If yes, provide the Hazard Zone: _____

22. Was the material shipped under an Exemption, Approval, or Competent Authority Certificate? ☐ Yes ☐ No

If yes, provide the Exemption, Approval, or CA number: _____

23. Was this an undeclared hazardous materials shipment? ☐ Yes ☐ No

Form DOT F 5800.1 (01-2004) Page 1 Reproduction of this form is permitted

Section 171.16 of the hazardous materials regulations requires a written report within 30 days of the hazmat incident. Filling out the requested information on the report form DOT F 5800.1 is expected to take 96 minutes. The hazardous materials incident report form can be submitted handwritten or electronically but not both. A copy of the report or an electronic image of the report must be retained for a period of two years post submission.

Immediate reporting is mandated for incidents involving hazardous material during transportation where certain events occur. These events include a person being hospitalized, the general public being evacuated for one hour or more, a person being killed, one or more transportation arteries being closed for one hour or more, and fire, spillage, breakage or suspected contamination involving a radioactive material.

In order to contribute to continual safety improvements, additional information must be provided for up to one year after the initial report filing. This requirement holds true as more information is gained or new developments arise. Examples include damage, loss or related costs not known originally or revised estimates of damages, related costs and losses resulting in a change of greater than 10% of the original estimates or $25,000. Other examples include, a person dying as a result of injuries caused by hazardous material or if the hazardous material or package information was misidentified.

PHMSA-05-22461

The Hazardous Materials Safety and Security Reauthorization Act (Title VII of SAFETEA-LU) was enacted on August 10, 2005. This action revised the maximum and minimum civil penalties and the maximum criminal penalty for violations of the federal hazardous materials transportation law or any regulation, order, special permit or approval under it. The Pipeline and Hazardous Materials Safety Administration (PHMSA) revised the regulations that pertained to the minimum and maximum civil penalties and the maximum criminal penalties to reflect the aforementioned Act. The PHMSA rule was effective on February 17, 2006.[19]

The PHMSA decreased the minimum civil penalty from $275 to $250. An exception to this change was for violations related to training. The updated minimum civil penalty for training violations was set at $450.

For a known violation, the maximum civil penalty was increased from $32,500 to $50,000. If the violation results in serious injury or illness to any person, substantial destruction of property or death, the maximum civil penalty is $100,000.

Criminal penalties now apply to both willful and reckless violations of federal hazardous material law or regulations. The maximum criminal penalty is five years imprisonment and, in accordance with Title 18 of the US Code, a fine of $250,000 for an individual or $500,000 for a corporation. The only change in this statute was to increase the maximum imprisonment time to ten years if a violation involves the release of a hazardous material which results in bodily injury to a person or death. Table 7 highlights many of the violation areas that could occur in nuclear pharmacy practice.[7,18] For example, failure to include an RQ designation would yield a baseline assessment of $500 and failure to use a tamper resistant device, $2,000. [7,19]

Table 7

Select frequently cited DOT violations[7,19]		
Violation Description	**49 CFR Citation**	**Baseline Assessment**
Failure to execute a shipping paper for a shipment of hazardous materials	172.201	$3,000 to $6,000
Failure to retain shipping papers appropriately	172.201 (e)	$1,000
Failure to include proper shipping name or incorrect shipping name	172.202	$800 to $1,600
Failure to include a hazard class	172.202	$1,000 to $2,000
Failure to include RQ	172.203(c)	$500
Using a shipping description for Class 7 material that fails to contain information or contains incorrect information	172.203 (d)	$2,000 to $4,000
Failure to sign a shipper's declaration	172.204	$800
Failure to mark package in letters 13mm high Type A	172.310(b)	$800
Placing a label on Class 7 that underestimates the category	172.403	$5,000
No emergency response telephone number	172.604	$2,600
Failure to train hazmat employees in the required areas of training recurrently	172.702	$450 and up in each area not covered
Failure to provide initial training in the required areas of training	172.702	> 10 = $700 each person in each area not covered < 10 = $450 each person in each area not covered
No tamper resistant device	173.412 (a)	$2,000
Offering a package without determining the level of removable contamination or exceeds level	173.443	$5,000 and up
Transporting packages of hazardous material which have not been secured against movement	177.834(a) and (g)	$3,000

INSPECTION GUIDANCE

The DOT may inspect both shippers and carriers of hazardous materials. In accordance with the July 2, 1979 Memorandum of Understanding, the NRC may conduct inspections of licensees regarding the requirements of the DOT. Inspections may occur at any time,[3] thus it is important to always be prepared for this process.

Keeping organized records is paramount to the successful outcome of an inspection. Records must be easily retrieved at the request of an inspector. It is important to understand and implement the proper retention times for transportation related documentation.

Inspectors should be asked for proper identification upon their arrival and be escorted during the course of their inspection. Leaving inspectors unattended or giving stacks of unwanted paperwork/documentation is ill-advised.

Questions posed by inspectors should be regulatory based. Any hazmat employee can be asked questions and should be prepared to respond. Remaining calm and asking for clarification when needed are recommended methods for responding to inspection questions. The right to appeal findings and fines assessed from inspections is always an option for shippers, carriers and licensees.

While inspections can occur at any time and any item related to the transportation of hazardous materials is subject to inspection, there are some times and items with increased likelihood and commonality. Likely times for inspection include: (a) post accidents; (b) post reporting to the NRC/agreement state; (c) on or near the anniversary of prior inspections; (d) post hospital inspections; and (e) post commercial carrier inspection. Common items inspected include training records, bills of lading, package certifications, emergency procedures, conditions of packages, vehicles used for transport, knowledge of hazmat employees and removal of old or incorporation of new rules and regulations.

Inspections should not be looked upon as negative experiences. Instead, they should be seen as a reflection of the past and current ability of the carrier/shipper/licensee to interpret and incorporate the rules and regulations pertaining to hazardous materials transportation. No matter the outcome, inspections should be used as a learning tool. Reviewing frequently cited violations and updates on rules and regulations can bring to focus areas of increased importance during inspections.

KEY HAZARD COMMUNICATIONS FOR CLASS 7

There is a vast amount of information present in the rules and regulations regarding the transportation of hazardous material. This section is meant to highlight some key communication regarding this information as it pertains to Class 7 radioactive materials.

Package and Vehicle Radiation Level Limits

The package and vehicle radiation level limits are found in 49 CFR 173.441.[7] This regulation describes the package limits for transport via non-exclusive vehicles as follow: external surface = 2 mSv/h (200

mRem/h), Transport Index = 10 and Criticality Safety Index (CSI) = 50. Further, they show the roadway limits as 50 for the sum of the package TI's and 50 for the sum of the package CSI's.

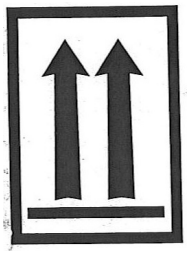
Marking

Package marking information can be found in 49 CFR Part 172, Subpart D.[7] Markings that are always required for non-bulk packages are the proper shipping name and the UN identification number. Additional package-based marking requirements are: the type of package (e.g., Type A), and the International Vehicle Registration Code for country of origin (e.g., USA). For specification 7A packagings this translates into:

USA DOT 7A Type A

Additionally, there are markings that are materials--based requirements. These are: (a) the gross weight (e.g.,, when the package weighs more than 50 kg (110 pounds), which is marked on the outside of the package, (b) underlined double arrows indicating upright orientation on two opposite sides to indicate liquid and, (c) the letters "RQ" in association with the proper shipping name when the package contains "RQ" levels of a hazardous substance (e.g., ≥ 0.37 GBq of I-131 or I-123). Figure 10 shows the package orientation arrows and can remain on a package if it contains both liquids and solids.

Figure 10: Package Orientation Arrow



Certain markings are considered to be optional. These include both the name and address of the consignor and consignee. While these are not required, they are recommended. Whether required or optional, all markings must be: (a) isolated from other marks, (b) unobscured by labels or attachments, (c) displayed on a background of sharp contrasting color, and (d) durable printed in English on a package surface, label, tag or sign.

Labeling

The labeling requirements for radioactive packages are found in 49 CFR, Subpart E.[7] Labeling is required to be: (a) representative of the hazmat contents of the package, (b) within color, design and size tolerance, (c) in contrast with its background, (d) unobscured by markings or attachments, (e) multiple labels must be within 150 mm of each other, (f) printed or affixed to the package surface (not

the bottom), and (g) placed near the proper shipping name marking. Radioactive material must have two radioactive warning labels affixed on opposite sides of the package. The label category to apply is determined by the maximum radiation level on the package surface and TI at one meter. Table 8 details how to determine the label category.[7]

Table 8

Determination of label category for packages[7]		
Label Category	**Maximum radiation level on the external surface**	**Transport Index**
White I	Less than or equal to 0.005 mSv/h (0.5 mRem/h)	0
Yellow II	Greater than 0.005 mSv/h (0.5 mRem/h) but less than or equal to 0.5 mSv/h (50 mRem/h)	More than 0 but not more than 1
Yellow III	Greater than 0.5 mSv/h (50 mRem/h) but less than or equal to 2 mSv/h (200 mRem/h)	More than 1 but not more than 10

When the TI is 0 (note; if the measured dose rate at one meter is not greater than 0.05, the TI value may be considered 0), it is not necessary to enter it on the hazard warning label. Radioactive White I is the lowest category label and has minimal radiation levels detectable outside the package, while Radioactive Yellow III has the highest radiation levels detectable outside the package and is the highest category.

The contents on the radioactive label must be entered using a durable, weather-resistant means. The contents must contain the names of the radionuclides. Symbols such as F-18 are acceptable. Further, it must contain the total activity of radionuclides in the package expressed in SI units (e.g., Bq, GBq). Customary units are permitted to follow the SI units if contained in parentheses. The Transport Index (TI) is entered only on Yellow II and Yellow III labels. Figure 11 shows a completed Yellow II label. The Criticality Safety Index (CSI) is entered only on a fissile label.

Figure 11: Completed Yellow II Hazard Warning Label

Excepted packages are excepted from labeling. However, they must be marked with UN 2910 and as "radioactive." Further, they must meet external contamination limits, the radiation level must be $\leq$ 0.005 mSv/h (0.5 mRem/h) at any external surface and

the contents must not exceed the limited quantity amounts based on table 173.435..

Vehicle placards

Placards are signs affixed to the exterior of a vehicle to identify hazards associated with the cargo. Placards are required for any vehicle containing a package with a Yellow III label. Placards are required to be displayed on all four sides of a vehicle. In contrast, labels and markings are used to indicate the level of radiation emitted and to show the quantity of radioactivity in a package. Table 9 explains the applicable topics for placard and label terminology. The term placard should never be used to describe a hazardous material warning label or marking.

Table 9

Differentiation Between Labels And Placards	
Terminology	**Applicability**
Labels	Packages
Markings	Packages
Placards	Vehicles

Shipping Papers

Information regarding shipping papers is described in 49 CFR Part 172, Subpart C.[7] Similar to markings, are entries on shipping papers may be always required, sometimes required, or optional. The entries which are always required are: Proper Shipping Name; Hazard Class 7; UN identification number; proper page numbering (i.e,. page 2 of 2); 24 hour emergency response phone number; total quantity of material in appropriate units (i.e., activity); number and type of packages; name of each radionuclide; the activity of each radionuclide (abbreviations are authorized) in SI units (may be followed by customary units in parentheses); description of chemical and physical form; the category of label used; the transport index of each package (Yellow II and Yellow III); shipper's certification and signature. Note the 24-hour phone number does not permit use of a number that requires a call back such as an answering machine. Also, the signature of the shipper can be legibly signed by mechanical means or manually.

A materials-based requirement that is sometimes required is the RQ designation. It is entered as part of the basic description (i.e., Proper shipping name, hazard class 7, UN number). An optional entry is the emergency response information. It may be entered on the shipping papers or may be a separate document carried with the shipping papers.

SUMMARY

Hazmat employees and employers have responsibilities for the safe transportation of hazardous materials in commerce that depend on a plethora of accurate and complete information. This information is provided via the DOT rules and regulations and periodic updates in the *Federal Register*. It is the duty of hazmat employees and employers to interpret and apply the rules and regulations correctly to ensure that the stellar safety record of radioactive materials transportation continues well into the future.

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QUESTIONS

1. If the maximum dose rate at one meter from a package surface is 1.12, what is the TI?
    a. 1.0
    b. 1.1
    c. 2.0
    d. 1.2

2. Which part of 49 CFR contains information regarding blocking and bracing?
    a. 177
    b. 173
    c. 178
    d. 172

3. Which of the following is the A_2 value for Molybdenum 99?
    a. 0.37 TBq
    b. 0.74 TBq
    c. 3.7 TBq
    d. 7.4 TBq

4. Which of the following is a pre-transportation function?
    a. storage incidental to movement
    b. preparing shipping papers
    c. movement of packages
    d. loading and unloading

5. What is the baseline assessment for placing a label on Class 7 package that underestimates the category?
    a. $500
    b. $250
    c. $1,500
    d. $5,000

6. What legislation established the Department of Transportation?
    a. Department of Transportation Act of 1966
    b. Hazardous Materials Transportation Act of 1974
    c. IAEA Safety Series Number 6
    d. Hazardous Materials Uniform Safety Act of 1990

7. What is the proper retention time of shipping papers by carriers?
    a. Three years
    b. Two years
    c. One year
    d. 375 days

8. At which level are most citations of regulations cited?
    a. Title
    b. Chapter
    c. Part
    d. Section

9. The proper area of package surface to wipe-test for contamination is_____.
    a. 50 cm^2
    b. 300 cm^2
    c. 200 cm^2
    d. 100 cm^2

10. What is the minimum separation distance between RAM packages with TI's of 1.1, 1.4, 2.6 and 3.0, from an aircraft crew?
    a. 0.9 m
    b. 0.3 m
    c. 155 cm
    d. 115 cm

11. When a violation of hazardous materials laws or regulations results in a death, the maximum imprisonment time and fine for an individual is _____?
    a. 5 years and $250,000
    b. 10 years and $500,000
    c. 10 years and $250,000
    d. 5 years and $500,000

12. The minimum civil penalty for DOT training violations is _____ per occurance.
    a. $400
    b. $275
    c. $250
    d. $450

13. The mandate for listing SI units for domestic and internal shipments of RAM was effective _____.
    a. December 8, 1999
    b. December 21, 1990
    c. September 28, 1995
    d. April 1, 1997

14. What is the number of packages shipped annually which contain radioactive materials?
    a. Three million
    b. Ten million
    c. Sixty-seven million
    d. One hundred million

15. Which agency has the regulatory responsibility for safety in transporting all hazardous materials?
    a. IAEA
    b. NRC
    c. DOE
    d. DOT

16. Immediate reporting of a DOT hazmat incident is mandated when:
    a. The general public is evacuated for 30 minutes or more.
    b. There is suspected contamination with RAM.
    c. A transportation artery is closed for 30 minutes or more.
    d. An involved person is examined at a hospital.

17. Following a DOT hazmat incident occurrence, what is the maximum elapsed time within which a telephone report must be posted?
    a. 1 hour
    b. 12 hours
    c. 6 hours
    d. 24 hours

18. Which final rule added the topic of security to the hazmat employee training requirements?
    a. HM 223
    b. HM 232
    c. HM 240
    d. HM 229

19. Which of the following is the proper UN identification number for RAM packages?
    a. UN 2908
    b. UN 2982
    c. UN 2911
    d. UN 2915

20. Recurrent training for hazmat employees must occur every _____.
    a. Five years
    b. Six months
    c. Twelve months
    d. Three years

21. The _____ is used as the definitive guidance for package and overpack allowance on aircraft.
    a. Criticality Safety Index
    b. Hazard Warning Labeling

c. Transport Index
d. Hazard Class

22. Which final rule revised the shipping paper retention time?
    a. HM 240
    b. HM 223
    c. HM 229
    d. HM 230

23. What does the general awareness component of hazmat training cover?
    a. How to recognize and identify hazards
    b. Emergency response information
    c. Topics directly applicable to the functions performed
    d. Recognizing and responding to security threats

24. What is the limited quantity activity for Y-90?
    a. 0.03 TBq
    b. 0.3 TBq
    c. 0.003 TBq
    d. 0.00003 TBq

25. When is Title 10 CFR updated each year?
    a. October 1st
    b. July 1st
    c. January 1st
    d. April 1st