



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

400 Seventh Street, S.W.  
Washington, D.C. 20590

APR 18 2000

Sam H. Lott, Ph.D.  
Radiation Safety Officer  
Guidant Corporation  
8934 Kirby Drive  
Houston, Texas 77054

Ref. No. 00-0068

Dear Dr. Lott:

This is in response to your March 1, 2000, letter requesting clarification on the return shipment of a radiotherapy cartridge containing phosphorus-32 encapsulated in a nitinol (nickel-titanium) wire under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether the shipment of the returned cartridge containing the used wire (approximately 35 mCi) qualifies for transport by passenger-carrying aircraft under provisions in § 173.448(f) of the HMR.

According to your letter, the radiotherapy containing phosphorus-32 encapsulated in nickel-titanium wire is used in intravascular radiotherapy for prevention of restenosis following interventional procedures such as balloon angioplasty or stenting. The wire is contained and shielded in a replaceable cartridge that is inserted at the customer site in an afterloader for use. The system is used for 3-4 weeks in patient treatment and then the cartridge containing the used wire is exchanged for another cartridge containing a fresh wire.

Section 173.448(f) provides for the transportation of Class 7 (radioactive) materials by passenger-carrying aircraft if the material is intended for use in, or incident to, research, medical diagnosis or treatment. It is the opinion of this Office that the return shipment of the cartridge containing the used wire qualifies as material intended for use incident to medical diagnosis or treatment, and may be transported by passenger-carrying aircraft.

I hope this answers your inquiry.

Sincerely,

Delmer F. Billings  
Chief, Standards Development  
Office of Hazardous Materials Standards



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Mr. Edward T. Mazzullo, Director  
Office of Hazardous Materials Standards DHM-10  
Research and Special Program Administration  
400 7th Street, S.W.  
Washington, D.C. 20590-0001

Dear Mr. Mazzullo:

The Hazardous Material Transportation Regulations state in 49 CFR 173.448(f):

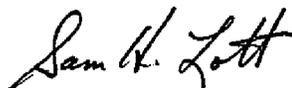
No person shall offer for transportation or transport aboard a passenger-carrying aircraft any Class 7 (radioactive) material unless that material is intended for use in, or incident to, research, medical diagnosis or treatment.

The above regulation was mandated by the Hazardous Material Transportation Act of 1974 (49 USC Section 5114).

Guidant Corporation is involved in intravascular radiotherapy for prevention of restenosis following interventional procedures such as balloon angioplasty or stenting. Outgoing shipments for radiotherapy contain phosphorus-32 encapsulated in a Nitinol (nickel-titanium) wire. The wire is contained (and shielded) in a replaceable cartridge that is inserted at the customer site in an afterloader for use. The system is used for 3-4 weeks in patient treatment and then the cartridge containing the decayed wire (approximately 35 mCi) is exchanged for another cartridge containing a fresh wire.

It is desired to facilitate return of the cartridge (includes the wire containing the decayed smaller activity radioactive material for ultimate disposal) for refurbishment and insertion of a new wire containing radioactive material. Does the shipment of the returned cartridge with the decayed smaller activity radioactive material qualify for transport in passenger-carrying aircraft?

Sincerely,



Sam H. Lott, Ph.D.  
Radiation Safety Officer  
Guidant Vascular Intervention  
713-218-9230

cc: Mr. Richard W. Boyle  
Mr. Wendell Carriker

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