



U.S. Department
of Transportation

Research and
Special Programs
Administration

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

AUG 12 1999

Mr. Richard E. Lisowski
Stored Energy Concepts, Inc.
P.O. Box 387
St. Peters, PA 19470-0387

Ref. No. 99-0116

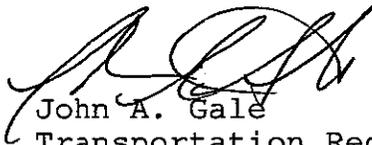
Dear Mr. Lisowski:

This is in response to your letter dated May 3, 1999 and telephone conversation with a member of my staff, regarding small quantity exceptions under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically you ask if your device classified as "Life-saving appliances, not self-inflating, Class 9, UN3072" may be shipped under the small quantity exception in § 173.4.

The answer is no. The 30 gram quantity limitation in § 173.4(a)(1)(ii) applies to the life saving appliance, not just the explosive component. Your life saving appliance, which was classified under an approval (EX9707049) as a Class 9, weighs more than 30 grams. The lifesaving appliance may only be shipped under the small quantity exception if the entire device meets the quantity limitations of 30 grams in § 173.4(a)(1)(ii).

I hope this satisfies your request.

Sincerely,

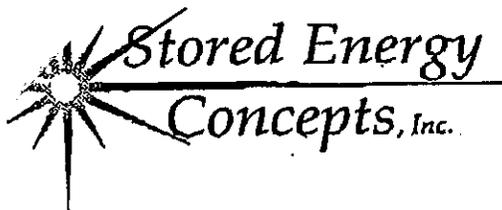


John A. Gale
Transportation Regulations Specialist
Office of Hazardous Materials Standards



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99-0116

May 3, 1999

U.S. Department of Transportation
400 Seventh Street S.W.
Washington, D.C. 20590
Standards Division
DHM-10 Room 8104

To Whom it may concern:

LIFECOR, INC. of 121 Freeport Rd, Pittsburgh, PA has retained my services with regard to applying for an exemption for their product in accordance with part 107.105 of 49CFR. LIFECOR manufactures a new cardiac defibrillator which is currently under FDA evaluation. The defibrillator, which is worn by the patient like a vest, has been classified as a Life Saving Appliance (not self inflating), UN3072, U.N. Classification Code 9, EX9707049, namely a Modified WCD Electrode Belt Assembly, LIFECOR part number 10A0265-A0. Each WCD belt assembly contains a maximum quantity of 0.18 grams of hazardous material. The Class 9 designation causes logistical problems in shipping to and from LIFECOR and patients or physicians. During my research of 49 CFR, I came across a small quantity exception, 173.4 of 49CFR.

Therefore, this letter is in reference to obtaining clarification of section 173.4 of 49 CFR, Small Quantities Exception. It is my understanding of this section that if one follows the limits for small quantity per package not to exceed 30 grams in accordance with section 173.4 and obtains package testing in accordance with 173.4 and marks the packaging in accordance with 173.4; then a Life Saving Appliance (not self inflating) UN3072 U.N. Classification Code 9, EX9707049, namely a Modified WCD Electrode Belt Assembly LIFECOR part number 10A0265-A0, may be offered for private or commercial shipment subject to no other requirements in the Hazardous Materials Regulations beyond those stated in 173.4. Could you please advise me in writing as to whether or not I have made the correct interpretation of this section? Thank you for your consideration of this matter.

Sincerely,

Richard E. Lisowski
President
Stored Energy Concepts, Inc.

