

Research and Special Programs

**Administration** 

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

NOV 2 4 1999

Ref. No. 99-0065

Ms. Catherine J. Feiock
QA Manager for Hospital Services
Sacremento Blood Center
1625 Stockton Boulevard
Sacramento, CA 95816-7089

Dear Ms. Feiock:

This is in response to your letter, and subsequent telephone conversations with members of this Office, concerning the air transportation of blood and blood components, packed with dry ice, under the International Air Transport Associations Dangerous Goods Regulations and the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). In telephone conversations with members of this Office, you stated the materials are biological products that are used for transfusions or for research purposes.

Your questions are paraphrased and answered as follows:

- Q1. Are absorbent materials (e.g., wipes) required for blood and blood components that have been tested and found not to contain an infectious substance?
- A1. Blood and blood components that do not contain an infectious substance or any other hazard class are not subject to the HMR or the international regulations, regardless of the quantity being shipped. However, blood and blood components may be subject to other Federal regulations, such as those for biological products administered by the Department of Health and Human Services' Food and Drug Administration. You should contact that agency for information on those requirements.
- Q2. What is the maximum volume of tested donor blood that can be shipped that is known to be non-infectious?
- A2. See above response under A1.
- Q3. What is the maximum volume of "Dry ice, 9, UN 1845, PG III" that may be included with a shipment of non-infectious frozen red blood cells?



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A3. With certain exceptions, the HMR authorize compliance with the International Civil Aviation Organization's (ICAO) Technical Instructions if the hazardous material is intended for transportation by aircraft, and by motor vehicle, either before or after being transported by aircraft. See 49 CFR 171.11. The entry "Carbon dioxide, solid or Dry ice" is listed in the § 172.101 Hazardous Materials Table of the HMR and the Dangerous Goods List in the ICAO Technical Instructions. Under these regulations, the maximum net amount of dry ice that may be offered in one package for transportation by aircraft is 200 kg (441 pounds). Advance arrangements must be made between the shipper and each carrier for shipments exceeding 2.3 kg (5 pounds) per package. See 49 CFR 173.217. Dry ice is subject to regulation only when transported by aircraft or vessel.

I hope this satisfies your request.

Sincerely,

Hattie L. Mitchell

Chief, Regulatory Review and Reinvention Office of Hazardous Materials Standards



## SACRAMENTO MEDICAL FOUNDATION

Blood Centers

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March 5, 1999

Edward Mazzullo
US Department of Transportation, Research Special Programs Administration
400 Seventh Street, South West, Room 8102
Route DHM 10
Washington, DC 20590-0001

Dear Mr. Mazzullo:

This letter is to confirm my understanding of answers received regarding IATA regulations:

SACRAMENTO BLOOD CENTER 1625 Stockton Boulevard Sacramento, CA 95816-7089 TEL 916/456-1500 FAX 916/452-9232

NORTH STATE BLOOD CENTER 1880 Park Marina Drive Redding, CA 96001 TEL 530/243-0160 FAX 530/243-0580

NORTH VALLEY BLOOD CENTER 285 Cohasset Road Chico, CA 95926 TEL 530/893-5433 FAX 530/893-2537

CENTER FOR BLOOD RESEARCH 1631 Stockton Boulevard Sacramento, CA 95816-7089 TEL 916/456-1500 FAX 916/456-2414 Q. Are absorbent wipes required for blood and blood components tested for infectious disease, non-reactive, transported via air?

A. No, tested blood and blood components are not regulated, only known pathogens.

Q. What is the maximum volume of tested blood which can be shipped?

A. No maximum volume, tested blood and blood components are not regulated.

Q. What is the maximum volume of dry ice that can be included with tested frozen blood component shipments (ORM UN1845)

A. 200 Kilograms per package or 440 lbs. (2.2 lbs. per kilogram)

Thank you for your prompt response and clarification of the requirements.

Sincerely,

Catherine J. Feiock

QA Manager for Hospital Services

Catherine J. Feiock