



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

AUG 28 1998

Mr. Ray Crain
Teddy Bear Transport
Cook Children's Medical Center
13725 Stone Road
Burleson, TX 76028

Ref. No. 98-0258

Dear Mr. Crain:

This is in response to your letter of March 21, 1998, requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR parts 171-180) regarding the transportation of an incubator unit by aircraft. Specifically you request confirmation that a compressed gas mixture containing 800 ppm of nitric oxide in nitrogen may be transported under the provisions of § 175.10(a)(14).

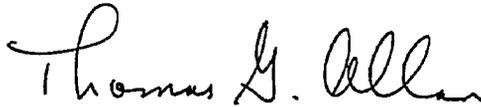
As provided by § 175.10(a)(14), a transport incubator unit necessary to protect life transported by aircraft is not regulated under the HMR when: (1) the compressed gas used to operate the unit is in an authorized DOT specification cylinder which is marked, labeled, filled and maintained as prescribed by the HMR; (2) any batteries used in its operation are of the non-spillable type; (3) the unit is constructed so that valves, fittings, and gauges are protected from damage; (4) the pilot in command is advised that the unit is onboard and when it is intended for use; (5) it is accompanied by a person qualified to operate it; (6) it is secured in the aircraft in a manner that does not restrict access to or use of any required emergency or regular exit or of the aisle in the passenger compartment; and (7) there is no smoking within ten feet of the unit.

A compressed gas mixture properly classed as Division 2.2 (non-flammable gas) is not regulated when transported by aircraft when the above conditions are met. It is the opinion

of this Office that a compressed gas mixture containing 800 ppm of nitric oxide in nitrogen is properly classed as Division 2.2. Therefore, you may transport the incubator unit as described above.

I hope this information is helpful.

Sincerely,

A handwritten signature in cursive script that reads "Thomas G. Allan".

Thomas G. Allan
Senior Transportation Specialist
Office of Hazardous Materials Standards

Teddy Bear Transport
801 Seventh Avenue
Fort Worth, Texas 76104-2798
817-886-5901

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CookChildren's

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\$175.10*

March 21, 1998

Dr. Richard Tarr
U.S. D.O.T.
400 7th Street, SW.
Washington, D.C. 20590-0001



Dear Sir,

To follow up on our telephone conversation last Friday 3/20/98, enclosed are copies of my correspondence with DOT on the Nitric Oxide issue so far.

If you have found that we do not require an exemption to carry and administer NO on board our aircraft, please send me a letter stating such with the reasons why. We need to provide documentation to the FAA and the part 135 Air Carrier who operates our aircraft. This will show that we will not be in violation of any hazardous material regulations when we use this on board the aircraft to treat some of our most critical Neo-Natal patients.

If you need any further information please call.

Sincerely,

98-0258

Ray Crain, Base Manager
Teddy Bear Transport
Cook Children's Medical Center

Spinks Airport,
13725 Stone Road,
Burleson, TX 76028.
(817) 447-2327 office
(817) 447-3137 fax

Enclosures

Teddy Bear Transport
 801 Seventh Avenue
 Fort Worth, Texas 76104-2706
 817-885-5901

CookChildren's

To Whom it may concern,
 12-23-96

My name is Frank Milano, manager of Respiratory Therapy for Cook Children's Teddy Bear Transport, a critical care neonatal and pediatric transport team in Fort Worth, Texas. I am writing you to obtain approval for our facility to transport using Nitric Oxide(NO), via air and ground medical transports.

Currently our facility, along with many major medical centers nation and world wide, is using NO on patients in our ICUs. This gas is being used experimentally with very positive results. NO produces very selective pulmonary vasodilation when inhaled which helps oxygen get to vital organs. The patients requiring this gas are very critical and need immediate attention due to failure of conventional treatments. Included, but not limited, are patients with persistent pulmonary hypertension, meconium aspiration, hyaline membrane disease and congenital diaphragmatic hernia. These patients have the greatest risk of mortality unless intervened with immediately.

NO, in it's pure form, is toxic and forbidden on moving vehicles. We will not be carrying NO in it's pure form. We will be carrying ^{A FEW} one tank of dilutional NO containing 400ppm(parts per million) secured in a canister specially made and permanently secured to our isolette system. NO is also a common air pollutant and is present in concentrations of 150-650ppm in cigarette smoke and up to 1200ppm in cigars and pipes. NO has been found to be produced in small quantities by our own bodies during inhalation.

The National Institute for Occupational Safety and Health and the Environmental Protection Agency have given a threshold limit value(TLV) as a time weighted average(TWA) of 25ppm for NO. The TLV-TWA is the concentration to which a person may be exposed continuously throughout a normal work week without adverse effects. Our patients will be started on 20ppm and reach a max of 80ppm(if necessary) to achieve desired effects, although the majority of babies will receive 20ppm or less.

Some hazards to patients receiving NO are pulmonary toxicity and methemoglobinemia. Pulmonary toxicity is associated with the conversion of NO to NO₂(Nitric Dioxide). When contamination of inspired gas has been carefully controlled, little evidence of toxicity exists at low concentrations. Studies have clarified this by controlling contamination of inhaled NO by NO₂. They report that when exposed to concentrations of 1000ppm for 30 minutes no pulmonary toxicity or lung damage occurs. Methemoglobinemia levels were followed and no significant increases were observed in patients breathing 20, 40, 80ppm for 10 minute periods.

Crew exposure would be very minimal. If a tank did suddenly empty into the air, it would be desirable to dilute the concentration of NO by circulating as much air as possible, open windows, turn on fans, etc. Other than this, little else would be medically necessary. Our aircraft has a complete molecule change out every 30 minutes due to pressurization of the cabin, so crew exposure would be very minimal even if a tank did suddenly discharge. If this would happen, the pressurization would be dropped, O₂ masks discharged and put on, ambient air analyzed, and patient care resumed. NO and NO₂ analyzers will be on board for continuous monitoring. In air at room temperature, NO at a concentration of 400ppm will be 50% oxidized to NO₂ in 9 minutes, and at a concentration of 10ppm it will take almost 7hrs to become 50% oxidized to NO₂.



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ppm
RC

Teddy Bear Transport
801 Seventh Avenue
Fort Worth, Texas 76104-2798
817-885-5901

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If you have any questions please feel free to contact me, Frank Milano, or our ^{BASE MGR} chief pilot, ~~Bob Veal~~, at 1-800-544-3075. Thank you for your consideration. This will be a great accomplishment for Cook Children's Teddy Bear Transport.

RAY CRAIN

Frank Milano RN, RRT
Frank Milano RN, RRT
Transport Therapist Manager
Teddy Bear Transport 