International Association of Fire Chiefs

4025 Fair Ridge Drive • Fairfax, VA 22033-2868 Telephone: (703) 273-0911
Fax: (703) 273-9363
Internet: www.iafc.org

August 15, 2003

Dockets Management Branch [HFA-305]
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03D-0165

The International Association of Fire Chiefs (IAFC) is privileged to represent the leaders and managers of America's fire service. The fire service consists of approximately 30,000 fire departments staffed by 1.1 million firefighters and emergency medical personnel; these men and women are the primary providers of Emergency Medical Services (EMS) in the United States.

Medical protocols often require EMS personnel to administer oxygen to patients in the field and during transport to a medical facility. Many fire departments and EMS agencies use and maintain a cascade system to fill oxygen cylinders. However, because of the limited nature of these systems—they only use one type of medical gas and fill only small cylinders—we feel that fire departments and EMS agencies should be exempted from some requirements in the proposed *Guidance for Industry* of the *Current Good Manufacturing Practice for Medical Gases* (CGMP) promulgated by the U.S. Food and Drug Administration (FDA).

The IAFC is pleased to note the definition of an EMS agency on line 1839 of the proposed CGMP is an accurate description of EMS agencies in the United States. On line 1673 of the proposed CGMP, the FDA recognizes the limited nature of medical gas transfilling associated with EMS operations and outlines a set of issues upon which EMS agencies should emphasize when establishing their system. We agree with all the areas of emphasis detailed in that section. However, this section does not specifically exempt EMS agencies from any of the requirements detailed in the CGMP that are not relevant to the limited scope of oxygen transfilling carried out by an EMS agency. We ask that EMS agencies be exempted from the following recommendations contained within the CGMP.

1. On line 401, under the section titled, "Prefill Inspections for Cylinders," the Agency recommends that all cylinders be vented of any remaining gases before being refilled. EMS agencies rarely take their cylinders down to atmospheric pressure in regular use. Because EMS agencies only fill their cylinders with oxygen, we are concerned that requiring all used bottles to be fully vented before refilling would result in a significant waste of product and create a higher likelihood of contaminants entering the bottle. In order to avoid these issues, EMS agencies should be exempted from this recommendation.

2. In addition, in the same section on line 414, the Agency recommends that the "Hammer" or "Dead Ring" test be used on empty cylinders. Because EMS agencies rarely fill empty cylinders, it is unlikely that this test will work effectively. We request that EMS agencies be exempted from this regulation as well.

3. Starting on line 977 under the section titled, "Testing for Release and Distribution," the CGMP states that, "For high-pressure cylinders filled on a multiple outlet manifold, the Agency recommends that one or more cylinders from each manifold filling sequence be assayed for identity, strength, and odor." Because EMS agencies only use medical oxygen that is supplied by a bulk distributor and is accompanied by a Certificate of Analysis (COA), we feel it is appropriate for EMS agencies to only perform a test for identity and odor on the cylinders from the manifold filling sequence.

I appreciate the opportunity to provide comments for your consideration and use.

Sincerely,

Garry L. Briese, CAE
Executive Director

GLB/mws