

SAFETY ALERT

EMERGENCY MEDICAL SERVICES FILLING OXYGEN OR AIR FOR HUMAN RESPIRATION

Through its member companies, the Compressed Gas Association (CGA) is aware that some emergency medical services (EMS) fill, transfill, or cascade oxygen USP, medical air USP, and breathing air cylinders for use in emergency response. Accidents have occurred and these activities expose EMS entities to substantial safety risks as well as potential regulatory and/or legal liabilities. CGA is concerned the safety risks and regulatory/legal liabilities may not be evident to the appropriate EMS authorities. Specific examples include but are not limited to the following:

- Transfilling of high pressure and cryogenic liquid compressed gases must be performed using filling equipment specifically designed for that purpose and shall take into consideration material compatibility, component pressure ratings, safety relief devices, pressure gauges, components cleaned for oxygen service, etc. Failure to consider the quality and integrity of the filling equipment can result in injury and death;
- Transfilling of high pressure compressed gas cylinders should only be performed by trained, qualified personnel who are familiar with the transfilling procedure and equipment, the precautions necessary to avoid the potential hazards associated with transfilling, and the procedures necessary to comply with the applicable government regulations. See CGA P-2.5, *Transfilling of High Pressure Gaseous Oxygen Used for Respiration* and CGA G-7, *Compressed Air for Human Respiration* [1, 2]. In Canada, also see CSA Z305.12, *Safe Storage, Handling, and Use of Portable Oxygen Systems in Residential Buildings and Health Care Facilities* and CSA Z180.1, *Compressed Breathing Air and Systems* [3, 4];
- Transfilling of liquid oxygen USP should only be performed by trained, qualified personnel who are familiar with the transfilling procedure and equipment, the precautions necessary to avoid the potential hazards associated with transfilling, and the procedures necessary to comply with the applicable government regulations. See CGA P-2.6, *Transfilling of Liquid Oxygen Used for Respiration* [5]. In Canada, also see CSA Z305.12, which addresses liquid oxygen [3];
- Regulatory considerations include U.S. Department of Transportation (DOT) requirements as defined in Title 49 of the U.S. *Code of Federal Regulations*, Part 173.301(e), and Transport Canada (TC) requirements as defined in CSA B340 [6, 7]. These regulations require that the filler of cylinders have the permission of the cylinder owner in writing before filling. EMS operations that fill cylinders they do not own or fill cylinders they do not have the owner's permission to fill are in violation of these regulations [6, 7];
- DOT and TC regulations also require cylinders be periodically inspected and retested as well as inspected for certain conditions prior to each fill to ensure cylinder integrity. Additionally, the DOT and TC specify certain recordkeeping requirements for the inspection, testing, and filling of high pressure gas cylinders and liquid oxygen containers;
- Depending on the scope of the transfilling activities, EMS entities may be defined as drug manufacturers by the U.S. Food and Drug Administration (FDA) if they fill oxygen USP or medical air USP. Medical gas manufacturers are required to register with FDA, list their products, and comply with all applicable requirements in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR), Parts 201, 205, 207 and the good manufacturing practices (GMP) in accordance with Parts 210 and 211 [8];
- GMP require specific and detailed written standard operating procedures (SOP) defining the prefill inspection, filling, post-fill inspection, testing, labeling, holding, and distribution of medical gases (oxygen USP, and medical air USP). The GMP also defines specific and extensive documentation of the medical gas filling operations as they are performed. EMS entities should ensure that their record keeping contain sufficient detail to meet the minimum requirements of the GMP;
- The U.S. *Food, Drug, and Cosmetic Act* and associated FDA regulations (21 CFR, Part 201) specify product labeling requirements [8]. It is a violation of federal law to refill cylinders with a product label that identifies another entity or gas supplier as the filler. EMS operations would be required to procure labels that specifically identify the EMS performing the filling operation. There may also be additional labeling requirements specified by other authorities, e.g., State Board of Pharmacy, that must be complied with; and

- See CGA C-7, *Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers*, for minimum labeling requirements including required label language [9].

To mitigate these safety and liability risks and comply with the applicable federal, state, provincial, and local regulations, EMS authorities should familiarize themselves with the applicable regulations and standards regarding the handling of high pressure gas cylinders and liquid oxygen containers and the filling of medical or other breathable gas products. EMS authorities are encouraged to obtain the standards referenced in this document. Questions regarding the filling, storage, handling, testing, labeling, and distribution of medical or breathing gases, should be discussed with your gas supplier.

References

Unless otherwise specified, the latest edition shall apply.

- [1] CGA P-2.5, *Transfilling of High Pressure Gaseous Oxygen Used for Respiration*, Compressed Gas Association, Inc., 14501 George Carter Way, Suite 103, Chantilly, VA 20151. www.cganet.com
- [2] CGA G-7, *Compressed Air for Human Respiration*, Compressed Gas Association, Inc., 14501 George Carter Way, Suite 103, Chantilly, VA 20151. www.cganet.com
- [3] CSA Z305.12, *Safe Storage, Handling, and Use of Portable Oxygen Systems in Residential Buildings and Health Care Facilities*, Canadian Standards Association, 5060 Spectrum Way, Mississauga, ON, Canada L4W5N6. www.csa.ca
- [4] CSA Z180.1, *Compressed Breathing Air and Systems*, Canadian Standards Association, 5060 Spectrum Way, Mississauga, ON, Canada L4W5N6. www.csa.ca
- [5] CGA P-2.6, *Transfilling of Liquid Oxygen Used for Respiration*, Compressed Gas Association, Inc., 14501 George Carter Way, Suite 103, Chantilly, VA 20151. www.cganet.com
- [6] *Code of Federal Regulations*, Title 49 Parts 100 to 180 (Transportation), Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. www.gpo.gov
- [7] CSA B340, *Selection and Use of Cylinders, Tubes and Spheres for the Transportation of Dangerous Goods, Class 2*, Canadian Standards Association, 5060 Spectrum Way, Mississauga, ON, Canada L4W5N6. www.csa.ca
- [8] *Code of Federal Regulations*, Title 21 (Food and Drugs), Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. www.gpo.gov
- [9] CGA C-7, *Guide to Preparation of Precautionary Labeling and Marking of Compressed Gas Containers*, Compressed Gas Association, Inc., 14501 George Carter Way, Suite 103, Chantilly, VA 20151. www.cganet.com

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