SAFETY ALERT

FILLING OF MEDICAL GASES BY EMERGENCY MEDICAL SERVICES

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. These activities expose EMS entities to substantial safety risks as well as 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:

− Accidents have occurred because the design of gas filling equipment did not 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 resulted 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 [1]. In Canada, see CSA Z305.12, Safe Storage, Handling, and Use of Portable Oxygen Systems in Residential Buildings and Health Care Facilities [2];

− 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), which specifically requires that the filler of DOT 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 this DOT regulation [3];

− DOT regulations include periodic retest and inspection criteria to ensure cylinder integrity. Both DOT and the U.S. Food and Drug Administration (FDA) specify certain recordkeeping requirements for the inspection, testing, and filling of high pressure and liquid gas cylinders;

− Depending on the scope of the transfilling activities, EMS entities may be defined as manufacturers by the FDA. Medical gas manufacturers are required to register with FDA, list their products, and comply with good manufacturing practices (GMP) in accordance with Title 21 of the U.S. Code of Federal Regulations (21 CFR), Parts 201, 205, 210, and 211 [4];

− GMP require specific written standard operating procedures (SOP) defining the prefill inspection, filling, postfill inspection, testing, labeling, holding, and distribution of medical gases (oxygen USP, medical air USP, and breathing air). EMS entities should ensure that their current SOP contain sufficient detail to meet the minimum requirements of the GMP [1]; and

− FDA regulations (21 CFR, Part 201) specify product labeling requirements. Of significant importance: EMS operations are not permitted to refill cylinders with a product label that identifies another entity or gas supplier as the filler. EMS operations are required to procure labels that specifically identify the EMS performing the filling operation. See CGA C-7, Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers, for specific labeling requirements including required label language [5].

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

References

Unless otherwise specified, the latest edition shall apply.


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NOTE—No technical information has been changed from the 2007 edition. This reaffirmed edition may include minor editorial changes.