

LIQUID OXYGEN USP WITHDRAWAL FROM HEALTH CARE FACILITIES' PRIMARY OR RESERVE BULK STORAGE TANK SYSTEMS

Alert to health care facilities

As per section 5.1.3.2.7 of NFPA 99, *Health Care Facilities Code*, 2012 Edition, the health care facility's primary or reserve bulk liquid oxygen USP storage tank system intended to supply gas to the facility shall not be used to transfill other liquid storage vessels [1].

Background

There is a growing demand for portable liquid oxygen USP as a mode of patient supply within hospitals and other health care facilities such as nursing homes, clinics, and hospices. At the same time, many of these facilities have begun to offer their own home respiratory care programs. These developments have prompted some health care facilities to request the suppliers of liquid oxygen USP to modify the health care facility's bulk liquid oxygen USP installation and equipment to permit the health care facility personnel to withdraw liquid oxygen USP from the bulk tank. These modifications are intended to permit filling of portable liquid oxygen USP vessels of various sizes, and/or home respiratory van/truck vehicle mounted cryogenic vessels.

There have been several incidents of property damage and personal injury associated with the improper transfilling of liquid oxygen USP from health care facilities' bulk liquid oxygen USP installations. CGA has published recommendations on the safe conduct of the transportation and transfilling of liquid oxygen USP in CGA SB-9, *Recommended Practice for the Outfitting and Operation of Vehicles Used in the Transportation and Transfilling of Liquid Oxygen Used for Respiration*, and in CGA P-2.6, *Standard for Transfilling of Liquid Oxygen Used for Respiration* [2, 3].

The purpose of this Safety Bulletin is to specifically caution health care facilities about additional hazards and risks that may be faced in such an activity. Most of the hazards attendant to transfilling liquid oxygen USP are absent when the health care facility uses the bulk liquid oxygen USP installation solely for its intended purpose—the supply of gaseous, oxygen USP to the health care facility's gas distribution piping system and ultimately to patients. However, when a health care facility attempts to use the bulk liquid oxygen USP system for transfilling, all of the attendant potential hazards are encountered. CGA SB-9 and CGA P-2.6 detail these hazards [2, 3].

In addition, dual use of a health care facility's bulk liquid oxygen USP system for supplying the gas distribution piping system and liquid oxygen USP transfilling is prohibited by NFPA 99 [1]. NFPA 99 establishes criteria to minimize the hazards of fire, explosion, and electricity for gas systems at health care facilities, section 5.1.3.2.7 stipulates that the facility shall not use the patient's cryogenic liquid oxygen USP storage to transfill other liquid oxygen USP storage vessels [1]. Transfilling can cause the system's alarms to activate (low pressure, reserve in use, reserve liquid level low, or other alarms) since the bulk liquid oxygen USP tank pressure can be affected by the transfill operation. The reserve supply, of the patients primary cryogenic liquid oxygen USP storage, shall be used solely for emergencies. NFPA 99 also stipulates that the reserve supply must contain an average day's supply at all times [1]. Withdrawal from the reserve supply vessel can rapidly reduce the amount of supply capacity to below the established "reserve liquid level low" alarm level. This low-liquid level can compromise the time required for the supplier to make a delivery and result in failure to maintain the prescribed capacity of the reserve supply for patient care.

The health care facility should also be aware of the increased potential for loss of supply of liquid oxygen USP contained in bulk tank systems when the system integrity is breached by permitting the transfilling of liquid oxygen USP from the bulk source to any other type of container.

Transfilling is a drug manufacturing step subject to U.S. Food and Drug Administration (FDA) registration and inspection, and subject to full compliance with regulatory mandated Current Good Manufacturing Practices (CGMP) found in 21 CFR Parts 210 and 211 [4]. The transfilling of liquid oxygen USP from the health care facility's bulk vessels into any other type of container can permit commingling of the bulk liquid oxygen USP with residues in the other receiving container, thereby destroying the USP compliance and certification of the bulk liquid oxygen USP remaining in the vessel. It must be kept in mind that this same bulk liquid oxygen USP vessel is usually in continuous use to supply gaseous oxygen USP to the health care facility's central piping system and ultimately directly to the patients. Any such product commingling in the bulk liquid oxygen USP system requires immediate requalification including product testing to re-establish conformance to the CGMPs. Failure to do so can create an adulterated and misbranded drug.

Recommendation to health care facilities

- Do not transfill liquid oxygen USP from your main or reserve bulk supply system into other portable liquid oxygen USP containers.
- Use a separate, dedicated cryogenic bulk vessel (not connected to the main or reserve supply) as the main storage unit at the facility from which liquid oxygen USP transfilling should be accomplished.
- Obtain full safety, handling, and transfill system operation training, and keep all employee training up-to-date to ensure safety and competency. Potential sources for this training include the liquid oxygen USP supplier or the equipment supplier.
- If the health care facility distributes transfilled liquid oxygen USP off the premises to homecare patients or other health care facilities, the health care facility is regarded by FDA as a drug manufacturer. The health care facility is advised to fully comply with the requirements of FDA as a drug manufacturer, which include registration of the health care facility as a drug manufacturing establishment, preparation of standard operating procedures, labeling, FDA inspection, compliance with analytical requirements, employee training, and record keeping. Regardless of the need to register, full compliance with FDA regulation is recommended. Additionally, NFPA 99 section 5.1.3.2.7 states "Cryogenic storage units intended to supply gas to the facility shall not be used to transfill other liquid storage vessels" [1].
- Do not fill containers without consent of the owner. Units classified as DOT specifications containers, filled with hazardous materials, may not be transported unless filled by or with consent of the owner as required in 49 CFR Part 173.301(e) [5].

References

Unless otherwise specified, the latest edition shall apply.

[1] NFPA 99, *Health Care Facilities Code*, 2012 Edition, National Fire Protection Association. www.nfpa.org

[2] CGA SB-9, *Recommended Practice for the Outfitting and Operation of Vehicles Used in the Transportation and Transfilling of Liquid Oxygen Used for Respiration*, Compressed Gas Association, Inc. www.cganet.com

[3] CGA P-2.6, *Standard for Transfilling of Liquid Oxygen Used for Respiration*, Compressed Gas Association, Inc. www.cganet.com

[4] *Code of Federal Regulations*, Title 21 (Food and Drugs), Superintendent of Documents, U.S. Government Printing Office. www.gpo.gov

[5] *Code of Federal Regulations*, Title 49 (Transportation), Superintendent of Documents, U.S. Government Printing Office. www.gpo.gov

Additional reference

Compressed Medical Gases Guideline, Food and Drug Administration, Division of Drug Information. www.fda.gov/Cder/guidance/cmvgg89.htm