

SAFETY ALERT

MEDICAL OXYGEN SUPPLY SYSTEM ISSUES DURING THE COVID-19 CRISIS

Health care facilities around the world are continuing to treat patients affected by the respiratory illness Coronavirus Disease 2019 (COVID-19). The increasing numbers of patients leads to a greater demand for medical gases, especially medical oxygen. Some health care facilities now require medical oxygen flow rates that are greater than the capacity of their existing medical oxygen supply systems. This leads to a need to increase the flow capacity of the medical oxygen supply system. Some new temporary health care facilities (i.e., field hospitals) are now coming on-line and need a temporary supply of medical oxygen.

Medical oxygen supply and delivery systems are not medical devices and accordingly are not subject to Emergency Use Authorization (EAU) requirements of the FDA. However, a risk assessment of measures taken to deal with the current emergency are necessary.

This Safety Alert addresses measures that may be considered to increase the capacity of existing medical oxygen supply systems. It also addresses measures that may be considered when installing temporary medical oxygen supply systems. The goal is to ensure that all measures considered provide a reliable medical oxygen supply system. The measures considered must not cause hazards to the health care facility patients, health care facility personnel, or medical gas supplier personnel. The recommendations in this safety alert may be followed until such time that the authority having jurisdiction (for example, World Health Organization, Public Health Agency of Canada, U.S. Centers for Disease Control and Prevention, or local authority) indicates that the crisis is no longer a public health threat.

The key piece of information for sizing a new medical oxygen supply system or for increasing the capacity of an existing supply system is the required flow of medical oxygen. The medical gas supplier should consult with the health care facility personnel to determine the expected increase in demand for oxygen. Sometimes health care personnel do not have complete details on flow or pressure requirements because they might not know these for ventilators or other medical equipment added to their systems. The documents *Medical Air and Oxygen Capacity* and *Sizing Medical Gases for COVID 19* provide expected flow and pressure demands for ventilators and other medical equipment [1, 2]. Medical gas suppliers should consider providing these documents to health care facility personnel so both can determine the expected medical oxygen flow and pressure requirements.

Health care personnel may also use these documents to assess the capacity of their existing internal medical oxygen piping systems to determine if larger piping is needed to supply the increased demand. Existing medical oxygen piping systems could have been designed for demand rates less than the current required flow rates and pressures. Smaller-than-optimal existing lines can have high pressure drops that do not allow the needed flow or pressures of medical gases.

Existing systems that are being used beyond the originally intended design flow must be carefully monitored for signs of failure to perform so that action can be taken before such a failure occurs. Fundamental to this is monitoring the medical oxygen pipeline pressure at the furthest use point. As oxygen use increases, it should be anticipated that the downstream pressure will begin to fall off from the desired operating pressure. Monitoring this trend is the most important data to be used in triggering mitigating actions. Additionally, the temperature of the oxygen supply entering the facility can drop. If heavy icing is observed up to the source valve on the medical oxygen supply system, a measurement of the gas temperature should be performed.

If the medical oxygen pipeline pressure is at risk of falling below the required operating pressure and/or the pipeline temperature of the supply gas entering the facility is colder than 20 degrees below the ambient temperature, the health care facility should contact the medical gas supplier immediately.

In such cases, the medical gas supplier, in consultation with the health care facility, should determine next steps. It might not be feasible to reduce the number of ventilators and medical equipment to a number that the existing medical oxygen pipeline can support. The use of cylinders at individual beds might not be a reasonable option

because of the need for frequent replacement of cylinders. According to *Medical Air and Oxygen Capacity*, a single patient at 40 liters per minute (LPM) will use 8 type K cylinders in a 24 hr period. Even if the oxygen demand is 20 LPM, the demand is still 4 cylinders per day. Maintaining that number of cylinders for multiple patients will be challenging. Cylinders should be considered only as a last resort. Health care facility personnel should consider the use of temporary supplemental supply lines to a group of patients. The supply lines can be piped either from the existing medical oxygen supply system or from a temporary supplemental supply system.

The health care facility may also use the documents referenced previously to determine the optimal size of medical gas piping at new facilities such as field hospitals. If health care facility personnel have questions about their medical gas piping, it is important to remind them that piping downstream of the source valve should be installed, where applicable, by personnel qualified in accordance with ASSE 6010, *Medical Gas Systems Installers* [3]. For systems in Canada, refer to CSA Z7396.1, *Medical Gas Pipeline Systems – Part 1: Pipelines for Medical Gases, Medical Vacuum, Medical Support Gases, and Anaesthetic Gas Scavenging Systems* [4].

Requirements for medical oxygen gas systems in the United States are found in NFPA 55, *Compressed Gases and Cryogenic Fluids Code* [5]. The same requirements are found in NFPA 99, *Health Care Facilities Code* and referenced in CSA Z7396.1 for medical gas supply systems in Canada [6, 4]. CGA M-1, *Standard for Medical Gas Supply Systems at Health Care Facilities* provides details on how to meet NFPA 55 and NFPA 99 requirements and other applicable regulations, *Federal Food, Drug, and Cosmetic Act* and Title 21 of the *U.S. Code of Federal Regulations* (21 CFR) Parts 210 to 211 for health care facilities in the United States [7, 8, 9].

Per NFPA 55 sections 1.1.1 and A.1.1.1, temporary supply systems shall meet the same performance requirements as permanent supply systems [5]. There are some exceptions to the prescriptive parts of NFPA 55 [5]. For example, there is no need to anchor delivery vehicles that are used as storage tanks.

Increasing the capacity of an existing medical oxygen supply system can require adding equipment such as storage tanks, regulators, and/or vaporizers. For a new health care facility, it will be necessary to install permanent or temporary equipment to serve as a medical oxygen supply system. Whether the supply system is an expanded or new system, the supply system might not meet all the requirements of NFPA 55, particularly the minimum separation distances from external exposures [5].

NFPA does not issue variances to its codes and standards. NFPA 55 is a model code that local municipalities (such as towns, cities, states, or parishes) can adopt, either as written or with changes [5]. In the case of a medical oxygen supply system that does not meet all of the NFPA 55 requirements, the medical gas supplier should work with the health care facility personnel and the local authority having jurisdiction (AHJ) to assess the safety of the proposed medical oxygen supply system and agree on any variances from NFPA 55 [5]. The three parties shall conduct a risk analysis of the impact of variances from NFPA 55 [5]. The risk analysis may be formal or informal in nature as determined by the three parties.

The rapid spread of the COVID-19 virus can lead to a need for fast installation of new medical oxygen supply systems or the upgrades of existing systems to increase their delivered flow or pressure. Medical gas suppliers should follow all external standards requirements and company procedures where applicable. However, actions that may be considered when time is of the essence include:

- An AHJ might give a verbal authorization to fill a new or upgraded supply system because it will take the AHJ time to provide written authorization. If possible, the AHJ should provide confirmation of the verbal authorization by text message or e-mail as soon as possible and follow up later with the formal written authorization;
- In the United States, a medical gas supplier might wish to use personnel who are not certified in accordance with either CGA M-1 or ASSE 6015, *Bulk Medical Gas/Cryogenic Fluid Central Supply Systems Installers* to install equipment under the direction of certified personnel [7, 10];
- In the United States, the health care facility might wish to use personnel who are not certified in accordance with ASSE 6010 to install medical gas piping under the direction of certified personnel [3]; and/or
- A medical gas supplier might use a smaller than optimal liquid storage tank for the main and/or reserve supply system because of demand for equipment.