Compressed Gas Association
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SAFETY ALERT

MEDICAL OXYGEN SUPPLY SYSTEM ISSUES DURING THE COVID-19 CRISIS

Health care facilities around the world are working 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 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.

The medical gas supplier, the health care facility personnel, and the AHJ should review any proposed time-saving steps and assess the risks and mitigation before taking action. Mitigation factors that might be considered include

higher-than-typical refill set points on the storage tanks, more frequent reporting of storage volume, and other methods to ensure reliability of the system.

When contemplating actions to increase an existing medical oxygen supply system's capacity, the medical gas supplier should determine the flow capacity of an existing medical oxygen supply system by considering all parts of the system:

- product vaporizer flow capacity;
- pressure building vaporizer capacity:
- product regulator flow rating;
- pressure building regulator flow rating; and
- piping pressure drop.

Typically, the product regulator and the vaporizer are the limiting factors, but all components should be investigated. The supplier should verify the limiting factor to ensure that work to upgrade the supply system is focused on the proper piece of equipment.

The following factors may be considered by the medical gas supplier when contemplating methods to increase the capacity of existing vaporizers:

- Determine the lowest allowable vaporizer outlet temperature for medical gases supplied to the health care facility. Many ventilators are designed for a minimum inlet temperature of 40 °F (5 °C). The health care facility should provide the temperature limits of ventilators or other medical equipment. Vaporizer outlet temperature may be colder if there is sufficient warming of the gas once it enters the facility. Minimum allowable vaporizer outlet temperature can also be limited by the design of piping supports within the facility, due to thermal contraction of piping;
- Determine if frosted medical oxygen supply lines can present problems from melting ice inside the health care facility;
- Determine if cold medical oxygen supply lines can present problems due to increased moisture condensation within the walls of the facility; and/or
- Ensure that increased oxygen flow through the vaporizers does not result in oxygen flow velocity that exceeds the maximum allowable velocity calculated per CGA G-4.4, *Oxygen Pipeline and Piping Systems* [11].

Where it is not possible to add vaporizers, the medical gas supplier may consider tracking ice buildup for determining when to perform periodic de-icing. Consider having customers, delivery vehicle personnel, and service technicians monitor ice buildup and notify medical gas suppliers of the need for vaporizer de-icing. De-icing work should follow these recommended practices:

- Work with established contract or medical gas supplier personnel who have standard operating procedures (SOPs);
- Minimize the number of people in the area who are exposed to steam, water, ice, and equipment;
- Have essential personnel wear appropriate personal protective equipment (PPE) such as hard hats, gloves, and other PPE as needed;
- Follow practices such as de-icing from the top downward to minimize the potential for falling ice;
- Minimize steam spray on aluminum surfaces to minimize damaging equipment;
- Evaluate the hazards associated with extended steam or water spray for de-icing, particularly during unattended operation; and
- Keep any gas-fired steam generators or other fuel-based de-icing heat sources at a safe distance from the oxygen supply system.

Medical oxygen supply systems typically use two parallel final line regulators to supply oxygen to the health care facility, with one set at a higher pressure than the other.

- Under normal conditions, NFPA 55 requires that each regulator be sized to meet the flow demand from the health care facility [5]. At increased flow rates, it might be necessary to operate both regulators at the same time, or the medical gas supplier might replace the existing regulators with higher capacity models. Using both regulators simultaneously to meet increased flow demand requires a risk analysis and approval by the AHJ because it is a deviation from code requirements. The medical gas supplier shall verify that the final line pressure relief device is adequately sized to protect downstream piping and equipment in the health care facility. Where the medical gas supplier cannot replace the regulators with higher-capacity models, the supplier should consider having replacement regulators or regulator parts of the current size available for replacing or repairing regulators that develop problems. Medical gas suppliers shall evaluate the final line pressure relief device flow capacity when installing higher capacity regulators;

- The medical gas supplier may consider increasing the regulator set points to provide more medical oxygen flow. The health care facility should monitor pressure at the farthest use point with oxygen flowing. In this case, the medical gas supplier and the health care facility personnel should review the high pressure alarm set point on ventilators or other hospital equipment to assess the potential high pressure from the regulators. As medical oxygen demands decrease at the end of the COVID-19 crisis, the medical gas supplier should change the regulators to their original pressure set points; and

- The medical gas supplier may consider increasing storage tank pressure. Higher storage tank pressure could increase flow through the pipeline regulators without changing their set pressures. Increasing the storage tank operating pressures might require increasing the “reserve in use” and “reserve low pressure” alarms as well as economizer set pressures. The effect of increased liquid saturation pressure on pressure building capacity should be considered.

The medical gas supplier sets the main tank low-level alarm and the reserve tank low-level alarm based on CGA M-1 and NFPA 55 requirements, health care facility flow demands, and the timing required for the medical gas supplier to deliver medical oxygen [7, 5]. The rapid change in flow demand means that the current alarm settings might not be the optimal settings. The medical gas supplier may consider reassessing the alarm set points in light of increased and variable flow patterns and change as necessary. As medical oxygen demands decrease at the end of the COVID-19 crisis, the medical gas supplier should change the set points to the appropriate levels.

Medical gas suppliers might consider converting equipment from use in industrial applications to use in medical oxygen supply systems. Suppliers shall ensure that equipment is suitable for oxygen service and has been cleaned in accordance with CGA G-4.1, *Cleaning of Equipment for Oxygen Service* or in accordance with supplier standards for oxygen cleaning [12]. Care shall be taken to remove all fluids used for oxygen cleaning from any added or modified equipment or piping before the system is put into service.

Consideration may be given by medical gas suppliers to connect temporary medical oxygen supply systems to the emergency oxygen supply connection (EOSC) or to other connections downstream of the existing system to supplement flow from the existing supply system. NFPA 55, NFPA 99, CSA Z7396.1, and CGA M-1 do not specifically address alarms for supplementary systems [5, 6, 4, 7]. The medical gas supplier, the health care facility, and the AHJ should review the additions to the medical oxygen supply system to determine if it is prudent to add alarms.

References

Unless otherwise specified, the latest edition shall apply.

[1] Edward (Sandy) Renshaw, P.E. *Medical Air and Oxygen Capacity*, Kaiser Permanente National Facilities Service Facilities Strategy Planning & Design. https://www.ashe.org/system/files/media/file/2020/04/KP-NFS-KaiserFSPDE-MedicalAirandOxygenCapacitypub20200329.pdf

[2] *Sizing Medical Gases for Covid 19*, BeaconMedaes. https://www.ashe.org/system/files/media/file/2020/04/MedGasSizing-updated.pdf

[3] ASSE 6010, *Medical Gas Systems Installers,* American Society of Sanitary Engineering. www.asse-plumbing.org

[4] CSA Z7396.1, *Medical Gas Pipeline Systems – Part 1: Pipelines for Medical Gases, Medical Vacuum, Medical Support Gases, and Anaesthetic Gas Scavenging Systems*, CSA Group. www.csagroup.org

[5] NFPA 55, *Compressed Gases and Cryogenic Fluids Code*, National Fire Protection Association. www.nfpa.org

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

[7] CGA M-1, *Standard for Medical Gas Supply Systems at Health Care Facilities*, Compressed Gas Association, Inc. www.cganet.com

[8] *Federal Food, Drug, and Cosmetic Act,* U.S. Food and Drug Administration. www.fda.gov

[9] *Code of Federal Regulations,* Title 21 (Food and Drugs) Parts 210 to 211, U.S. Government Printing Office. www.gpo.gov

[10] ASSE 6015, *Bulk Medical Gas/Cryogenic Fluid Central Supply Systems Installers,* American Society of Sanitary Engineering. www.asse-plumbing.org

[11] CGA G-4.4, *Oxygen Pipeline and Piping Systems*, Compressed Gas Association, Inc. www.cganet.com

[12] CGA G-4.1, *Cleaning of Equipment for Oxygen Service,* Compressed Gas Association, Inc. www.cganet.com

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