

SAFETY ALERT

CYLINDER AND CRYOGENIC CONTAINER ISSUE RELATED TO CYLINDER CONVERSION AND FILLING DURING THE COVID-19 CRISIS

As health care providers around the world work to assist patients affected by the respiratory illness Coronavirus Disease 2019 (COVID-19), the demand for medical gas containers will rise due to the increased need for these containers at both health care facilities and for patients requiring them for home use. It is important that any measures taken to address this increased demand and avoid any potential shortage on a temporary basis are done so in a manner that does not cause a safety hazard to the filler or unacceptable risk to the patients who are the ultimate consumer.

This Safety Alert will address interim measures that may be considered for use during this pandemic crisis, if there is a need to convert high pressure cylinders or large portable cryogenic containers from industrial service to medical service to alleviate a current or potential shortage. Typically, high pressure cylinders with between 100 to 300 cubic feet capacity and cryogenic containers between 160 and 230 liquid liters capacity are those generally converted. Small high pressure medical oxygen cylinders, such as “E” size, and small liquid oxygen containers used in patient homes, are already dedicated to medical service. This Safety Alert will also address interim cylinder filling measures that may be considered during this crisis to potentially allow more cylinders to be filled in a given period of time. Prior to considering the interim actions noted below, a firm should make every effort to meet the normal requirements of CGA standards through traditional resource planning and scheduling to provide for additional cylinder maintenance and cylinder filling capacity.

In 2018, CGA published the first edition of CGA M-18, *Standard for the Change of Product and Change of Grade for High Pressure and Refrigerated Liquid Containers* [1]. Although this publication addresses both processes, when additional medical cylinders/containers are needed, typically the less time-consuming change of grade process is considered before a change of product. Both processes require knowledgeable operators with documented education, training and experience, and following approved standard operating procedures (SOPs) to complete the change process.

In 2016, CGA published the fifth edition of CGA P-15, *Standard for the Filling of Industrial and Medical Nonflammable Compressed Gas Cylinders* [2]. For purposes of this Safety Alert, temporary considerations may be given to the filling standards specified in CGA P-15 that the filling facility, understanding the risks associated with any modifications made during this pandemic, may determine to take. In general, there are no specific temporary modifications to the filling process used for filling refrigerated liquid containers that would gain significant efficiencies in time needed to fill the container. A company’s SOPs for the filling and associated documentation of the filling process may require a written and approved deviation based on the temporary measure(s) a company may take during the COVID-19 crisis.

All current requirements for labeling, as specified in CGA C-7, *Guide to Classification and Labeling of Compressed Gases* must be followed, without exception for compliance with current DOT, OSHA, and FDA labeling requirements, including the requirement for proper 360-degree wrap around medical identification for large portable liquid containers in compliance with 21 CFR 201.328 [3, 4]. Labeling is the primary means of identification of a cylinder/container’s contents.

High pressure cylinders

- During the COVID-19 crisis, consideration may be given to not performing an internal inspection of a cylinder specified in CGA M-18, provided only a change of grade (e.g., industrial oxygen to medical oxygen) was performed, that is, not a change of product and the required odor test performed on the non-medical cylinder prior to conversion was acceptable.
- During the COVID-19 crisis, in accordance with the provisions of DOT Special Permit 21025, and if DOT has approved party status, or in accordance with the Notice of Enforcement Discretion Regarding Cylinders That Have Exceeded Their Requalification Test Date, issued by PHMSA on April 6, 2020, DOT specification

cylinders that are up to 12 months overdue for periodic requalification may be filled and shipped. Transport Canada has issued temporary certificate TU 0751 allowing the filling of certain cylinders past their inspection and test date, subject to specific conditions.

- During the COVID-19 crisis, consideration may be given to not painting a cylinder in accordance with the colors specified in CGA C-9, *Standard Color Marking of Compressed Gas Containers for Medical Use*, provided the medical gas labeling properly identifies the product as medical and preferably the label is color coded itself [5]. Color coding is only a tertiary means of identification. Consideration may be given to alternate means of color identification as opposed to painting the entire shoulder of the cylinder the specified color. These cylinders must be painted in accordance with the colors specified in CGA C-9, as soon as possible after the COVID-19 crisis has passed if cylinders remain in medical service.
- During the COVID-19 crisis, consideration may be given to not venting of residual medical gas and subsequent evacuation as specified in CGA P-15, provided all cylinders that will be refilled together on the same manifold all pass the requisite odor testing specified in CGA P-15. This process is sometimes referred to as "top-fill". Fill records shall document that these cylinders were not vented and evacuated. This exception would not be appropriate for the first medical fill of a manifold of cylinders if one or more of the cylinders to be filled had just undergone a change of grade or change of product process or if a cylinder was returned from a customer with no residual pressure.

Portable liquid cryogenic cylinders

- During the COVID-19 crisis, if conversion of portable liquid cryogenic cylinders from industrial service to medical service is necessary, only the change of grade process described in CGA M-18 should be considered.
- In 2000, CGA developed SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders*, now in its fourth edition, that discusses the types of devices to be used with industrial and medical cylinders respectively as tamper evident and tamper resistant [6].
- During the COVID-19 crisis, inventory of the medical tamper-resistant devices used to resist the gas use, liquid fill/withdrawal, and vent outlets from being changed could be insufficient. In those instances where a tamper-resistant device is not available, an industrial tamper-evident device may be used temporarily, provided the converted cylinder (converted per CGA M-18) complied with all medical labeling requirements specified in CGA-C-7 and reiterated in CGA SB-26. The company should consider additional risk mitigation strategies, such as additional labeling under each outlet warning against removal. In addition, users of these modified containers should be trained to verify that tamper evident devices are in place, showing no signs of tampering or attempted removal and in connecting liquid containers to utilization equipment and that training acknowledged.

References

Unless otherwise specified, the latest edition shall apply.

[1] CGA M-18, *Standard for the Change of Product and Change of Grade for High Pressure and Refrigerated Liquid Containers*, Compressed Gas Association, Inc. www.cganet.com

[2] CGA P-15, *Standard for the Filling of Industrial and Medical Nonflammable Compressed Gas Cylinders*, Compressed Gas Association, Inc. www.cganet.com

[3] CGA C-7, *Guide to Classification and Labeling of Compressed Gases*, Compressed Gas Association, Inc. www.cganet.com

[4] *Code of Federal Regulations*, Title 21 (Labor), U.S. Government Printing Office. www.gpo.gov

[5] CGA C-9, *Standard Color Marking of Compressed Gas Containers for Medical Use*, Compressed Gas Association, Inc. www.cganet.com

[6] CGA SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders*, Compressed Gas Association, Inc. www.cganet.com

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Work Item 20-96
Medical Gases Committee

FIRST EDITION: 2020 (Corrected 4/15/2020)

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