CGA M-14.1—2013
REAFFIRMED 2019

BULK TRAILER CHANGE OF GRADE VALIDATION PROTOCOL

FIRST EDITION

CGA
Compressed Gas Association
The Standard For Safety Since 1913

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Work Item 19-009
Medical Gases Committee

NOTE—Appendices A, B, C, D, E, F, G and H (Informative) and are for information only.

NOTE—No technical information has been changed from the 2013 edition. This reaffirmed edition may include minor editorial changes.

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1 Introduction

This publication describes the compressed gas industry's standard operating procedures for changing grade of bulk liquid oxygen and bulk liquid nitrogen trailers from nonmedical service to medical service. The intent of this publication is to validate that the procedure, as defined in CGA M-14, *Guideline for Bulk Liquid Oxygen and Bulk Liquid Nitrogen Trailer Change of Grade,* adequately changes the grade of product to ensure that the trailers are suitable to receive medical grade product [1].[1]

2 Scope

The scope of this publication is the qualification of the change of grade (COG) process, which involves the conversion of a nonmedical cryogenic transport trailer to medical-grade. This includes converting trailers from:

- nonmedical oxygen to oxygen, USP; and
- nonmedical nitrogen to nitrogen, NF.

This publication is limited to a COG using the purge methods identified in CGA M-14, where the nonmedical grade product is replaced by a medical grade product [1].

This publication does not apply to trailers that undergo a change of service from one product to another product such as oxygen to nitrogen, nitrogen to oxygen, etc.

The medical liquid products included within the scope of this validation are oxygen, USP and nitrogen, NF.

3 Purpose

The purpose of this publication is to set forth the methodology which will be used to show the effectiveness of the COG for a liquid trailer from nonmedical grade product to a medical grade product.

4 Process description

The process of preparing a trailer for medical liquid service involves the removal of the residual nonmedical grade product from the trailer and replacing it with a medical grade product. This validation process will demonstrate that a trailer, which the firms consider liquid empty when properly purged with medical liquid/gas can meet the firm's medical product release specifications. This process involves the cyclical purging of the trailer using medical liquid/gas to replace the nonmedical grade product.

A risk assessment was conducted to identify the critical components of the COG process. The test protocols in this validation study were developed to document that the controls, which are in place are adequate to assure that the COG process performs as intended for replacing the nonmedical grade product from the trailer and that no unexpected results will occur.

5 Risk assessment summary

The risk assessments conducted by members of the Compressed Gas Association (CGA) showed that there were seven steps that had a risk index of 6 or higher that needed further evaluation:

- inadequate venting—operator error;
- valve freezing;
- warm trailer;
- equipment failure—safety or rupture disk failure;
- not following procedure—residual product still in trailer;

[1] References are shown by bracketed numbers and are listed in order of appearance in the references section.