

**CGA M-7—2014**

**GUIDELINE FOR QUALIFYING  
SUPPLIERS USED BY MEDICAL  
GAS MANUFACTURERS  
AND DISTRIBUTORS**

**FOURTH EDITION**

**CGA**  
Compressed Gas Association

*The Standard For Safety Since 1913*

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NOTE—Technical changes from the previous edition are underlined.

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

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## 1 Introduction

This publication provides guidance for medical gas manufacturers and/or distributors to follow when developing procedures for qualifying suppliers.

## 2 Scope

This publication is a guide for medical gas manufacturers and/or distributors developing company-specific standard operating procedures (SOP) for qualifying suppliers who provide medical gases, medical devices, equipment, components, or services.

It may be used when qualifying new suppliers or when requalifying existing suppliers of medical gases including other gases, which includes:

- original manufactures of medical oxygen, nitrogen, carbon dioxide, helium, nitrous oxide, and air by compression that swap with or directly supply to other original manufacturers or their customers;
- subsequent manufacturers of medical gases obtaining medical gases from an original manufacturer; and
- subsequent manufacturers of medical gases obtaining medical gases from another subsequent manufacturer.

## 3 Definitions

For the purpose of this publication, the following definitions apply.

### 3.1 Publication terminology

#### 3.1.1 Can

Indicates a possibility or ability.

#### 3.1.2 May

Indicate that the procedure is optional.

#### 3.1.3 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

#### 3.1.4 Should

Indicates that a procedure is recommended.

### 3.2 Technical definitions

#### 3.2.1 Assessment

Review to determine which purchased medical gases, medical equipment, products, components, or services can affect the identity, strength, quality, or purity of a medical gas.

#### 3.2.2 Conditional qualification

Supplier who has not been qualified but based on objective evidence can reasonably be expected to supply conforming material or services.

#### 3.2.3 Critical ranking

Rank assigned by a risk priority system and applied to a purchased product, component, and/or service as the result of the critical assessment review.

NOTE—Critical ranking can be assigned a numeric value.