

CGA

Compressed Gas Association

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CGA M-7—2022 **STANDARD FOR QUALIFYING** **SUPPLIERS USED BY MEDICAL** **GAS MANUFACTURERS,** **EQUIPMENT MANUFACTURERS,** **AND DISTRIBUTORS**

SIXTH EDITION

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Work Item 23-028
Medical Gases Committee

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, medical gas equipment manufactures, and distributors to follow when developing procedures for qualifying suppliers who provide medical gases and/or medical equipment, parts, or services, including the services of contract drivers delivering medical gases.

2 Scope

This publication applies to medical gas manufacturers, medical gas equipment manufactures, and distributors developing company-specific standard operating procedures (SOP) for qualifying suppliers who provide medical gases and/or, medical devices, equipment, components, or services, including the services of contract drivers delivering medical gases.

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

- original manufacturers 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;
- subsequent manufacturers of medical gases obtaining medical gases from another subsequent manufacturer; and
- original manufacturers of medical gases obtaining feed gas sources for their purification processes.

3 Definitions

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

3.1 Publication terminology

3.1.1 Shall

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

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

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.