



CGA M-8—2018
STANDARD FOR THE
MANUFACTURER OF
CALIBRATION GAS
STANDARDS USED TO
ANALYZE MEDICAL AND
FOOD GASES

THIRD EDITION

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Work Item 16-042
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendix A (Normative) is a requirement.

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1 Introduction

This publication establishes the minimum requirements for the manufacture, analysis, and qualification of calibration gas standards used to qualify gases regulated by the U.S. Food and Drug Administration (FDA) or Health Canada (HC). The intent of this publication is to ensure consistent manufacture of calibration gas standards.

For the purpose of this publication, the term manufacturer shall mean calibration gas manufacturer unless it is preceded by a specific qualifier, e.g., equipment manufacturer.

2 Scope

This publication applies to the manufacture, analysis, and qualification of primary gas standards used to calibrate analytical equipment used to verify the concentration of standards. It also applies to the manufacture and analysis of certified gas standards used to calibrate analytical instruments used to test FDA or HC regulated gases.

This publication does not apply to the manufacture of calibration gas standards classified as medical devices.

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

Indicate 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 Accuracy

Degree of conformity of a measured or calculated quantity to its actual (true) value.

3.2.2 Absolute

Degree of variance independent of comparison to a reported value.

NOTE—For example, if the reported concentration of a gas standard is $5\% \pm 2\%$ absolute, the actual concentration lies in the range of 3% to 7%.

3.2.3 Relative

Degree of variance dependent on comparison to a reported value.

NOTE—For example, if the reported concentration of a gas standard is $5\% \pm 2\%$ relative, the actual concentration lies in the range of 4.9% to 5.1%, which is $5\% \pm (2\% \text{ of } 5\%)$ or $5\% \pm 0.1\%$ absolute.