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STANDARD FOR THE MANUFACTURER OF CALIBRATION GAS STANDARDS USED TO ANALYZE MEDICAL AND FOOD GASES

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Work Item 23-003
Medical Gases Committee

NOTE—No technical information has been changed from the 2018 edition. This reaffirmed edition may include minor editorial changes.

NOTE—Appendix A (Normative) is a requirement.

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SECOND EDITION: 2011
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Appendix

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 or 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% ± 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% ± 2% relative, the actual concentration lies in the range of 4.9% to 5.1%, which is 5% ± (2% of 5%) or 5% ± 0.1% absolute.