

CGA M-13—2020

GUIDELINE FOR  
QUALIFYING THIRD-PARTY  
TESTING LABORATORIES

THIRD 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 and B (Informative) are for information only.

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## 1 Introduction

This publication describes a method that can be used to qualify third-party testing laboratories for compliance with current good manufacturing practices (CGMP/GMP) and good laboratory practice standards.

## 2 Scope

This publication describes the minimum criteria for qualifying third-party testing laboratories that provide analytical testing services for medical gases.

## 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. [end of PC 35892]

### 3.2 Technical definitions

#### 3.2.1 Requester

Medical gas manufacturer or medical gas user.

## 4 Qualification

### 4.1 Criteria

Third-party testing laboratories shall demonstrate competencies for gas testing and comply with applicable regulatory standards including:

- compliance with CGMP/GMP, current good laboratory practices (CGLP), and current good documentation practices (CGDP);
- registration, permitting, and licensing required by the federal, state, provincial, territorial, and local authorities;
- quality management system (QMS) that ensures the applicability and validity of test results including management of change procedures;
- ability to demonstrate that personnel involved in any aspect of medical gas testing have the proper training and qualifications to consistently perform the tasks assigned to them;
- laboratory equipment that is validated and qualified to perform the testing requested;