

CGA M-13—2020

**GUIDELINE FOR
QUALIFYING THIRD-PARTY
TESTING LABORATORIES**

THIRD EDITION

CGA
Compressed Gas Association

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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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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Definitions.....	1
4 Qualification.....	1
4.1 Criteria.....	1
4.2 Procedure	2
4.3 Maintaining qualification	2
5 Third-party testing	2
5.1 Documentation	2
5.2 Quality management system.....	3
5.3 Personnel qualifications and training.....	4
5.4 Recordkeeping	4
6 Canadian regulations and guidance.....	4
6.1 Regulations.....	4
6.2 Guidance	4
7 References	5
Appendices	
Appendix A—Example of a laboratory qualification checklist (Informative)	6
Appendix B—Example of a laboratory qualification audit form (Informative)	7

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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;
- a 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;