

CGA M-13—2014

**CERTIFYING THIRD-PARTY
TESTING LABORATORIES**

SECOND EDITION



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 certify third-party testing laboratories for compliance with current good manufacturing practices (CGMP/GMP) and good laboratory practice standards.

For the purpose of this publication, the term requester refers to both medical gas manufacturers and medical gas users.

2 Scope

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

3 Certification

3.1 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;
- appropriate document control and security policies and procedures; and
- acceptable quality history.

A requester shall also ensure that a third-party testing laboratory:

- meets any insurance requirements specified by the requester;
- has a compatible business fit with the requester;
- has an acceptable safety record; and
- has a qualification procedure.

3.2 Procedure

The following steps shall be completed when certifying a third-party testing laboratory:

- a) The third-party testing laboratory submits a completed checklist to the requester for review (see Appendix A for an example of a laboratory certification checklist);
- b) The requester reviews the checklist to ensure that it is complete and meets all of the requirements;