CGA M-4—2012

VALIDATION OF MEDICAL CYLINDER FILLING SYSTEMS

FIRST EDITION

COMPRESSED GAS ASSOCIATION, INC.

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NOTE—Appendices A, B, C, D, E, F, G, and H (Informative) are for information only.

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1 Introduction

This publication provides guidance for validating typical compressed medical gas (CMG) cylinder filling systems. Variations from the processes described can exist. Firms shall assess these variations and determine if deviations from this guidance are necessary.

The approach and activities in this publication are designed to ensure that CMGs have the claimed identity, strength, quality, and purity. Validation through scientific, documented studies is intended to show that a given utility, system, process, or piece of equipment:

- meets the design specification for its critical elements;
- is properly installed, operated, and maintained;
- is suitable for its intended application;
- conforms to current good manufacturing practices (CGMP/GMP) criteria as defined by applicable regulatory agencies, for example U.S. Food and Drug Administration (FDA) and Health Canada; (HC) and
- is capable of consistently producing a product that meets all predetermined specifications and quality attributes.

2 Scope

This publication provides validation guidance for CMG manufacturing operation at container filling facilities, typically referred to as cylinder filling or packaged gas operations. These container filling operations include high pressure cylinder filling operations, portable cryogenic container filling operations, and small bulk container (for example, vehicle mounted vessel) filling operations.

This publication does not address validation of bulk manufacturing and trailer or railcar filling operations such as operations conducted at air separation plants. For information on bulk operations, see CGA P-8.2, *Guideline for Validation of Air Separation Unit and Cargo Tank Filling for Oxygen USP and Nitrogen NF* [1].[1]

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Calibration
Process by which an instrument of known accuracy or a certified standard is used to detect, report, or eliminate variation in the accuracy of the item being tested.

3.2 Change control
Formal monitoring program in which qualified representatives of appropriate disciplines review proposed or actual changes that can affect a validated status.

NOTE—Change control is often referred to as management of change.

3.3 Component
Supply gas or other ingredient intended for use in the manufacture of a medical gas.

3.4 Compressed medical gas (CMG)
Medical liquefied or vaporized gas alone or in combination with other gases that are drugs or devices as defined by the Federal *Food Drug and Cosmetic Act*, or other applicable regulations [2].

3.5 Concurrent validation
Establishing documented evidence that the process does what it purports to do based on information generated during actual operation of the process.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.