CGA P-8.2—2013

GUIDELINE FOR VALIDATION OF AIR SEPARATION UNIT AND CARGO TANK FILLING FOR OXYGEN USP AND NITROGEN NF

FIFTH EDITION

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Work Item 13-004
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendices A, B, and C (Informative) are for information only.

FIFTH EDITION: 2013
FOURTH EDITION: 2008
THIRD EDITION: 2003
SECOND EDITION: 2001

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1 Introduction

This publication provides the Compressed Gas Association (CGA) position and guidance on the manufacturing, bulk product storage, and cargo tank filling validation activities that take place at a typical air separation unit (ASU) that is manufacturing oxygen USP, nitrogen NF, or both [1].[1] Variations from the typical ASU process configurations can exist. Companies shall assess variations and determine if deviations from this guidance are necessary.

The approach and activities in this publication are designed to ensure that these gases, which are classified as drug products, have the claimed identity, strength, quality, and purity. Scientific, documented studies will show that the given utility, system, process, or piece of equipment:

- meets the specifications of its design for its critical elements;
- is properly installed, operated, and maintained;
- is suitable for its intended application;
- is in accordance with principles established and generally accepted by the compressed gas industry;
- meets the CGMP/GMP requirements;
- meets the principles of FDA's *Guidance for Industry, Process Validation General Principles and Practices*, and meets the Health Canada Validation Guidelines for Pharmaceutical Dosage Forms (GUIDE-0029) [2, 3]; and
- is capable of consistently producing a product that meets all predetermined specifications and quality attributes.

2 Scope

This publication addresses validation for ASU cryogenic manufacturing and cargo tank filling processes pertaining to oxygen USP and nitrogen NF.

3 Definitions

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

3.1 Automated loading

Computer assisted cargo tank filling system.

NOTE—The degree of assistance can vary based on the company and application.

3.2 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.

3.3 Change control

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

NOTE—The intent is to determine the need for action that would ensure and document that a system is maintained in a validated state as described in *Good Computer Validation Practices*, "Common Sense Interpretation" [4].

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