CGA

Compressed Gas Association

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STANDARD FOR MEDICAL GAS SUPPLY SYSTEMS AT HEALTH CARE FACILITIES

FOURTH EDITION

Approved American National Standard ANSI

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Work Item 18-027
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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

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Appendices

1 Introduction

Compressed medical gases (CMG) are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals.

Medical gas supply systems deliver CMG to piped distribution systems at health care facilities. Oxygen USP and medical air USP provide direct assistance for breathing and also assist in the delivery of medical treatment(s). Oxygen USP, medical air USP, and CMG mixtures are used in hyperbaric chambers. Nitrogen NF is used to operate power tools during patient care procedures. CMG shall be permitted to be supplied to the medical gas piped distribution system by cylinders or containers connected to a manifold system, a cryogenic fluid central supply (either a permanently installed bulk supply system or permanently installed microbulk supply system), or a temporary supply system.

Supplier-owned or health care facility-owned storage and control systems that supply CMG shall be installed and maintained in compliance with this standard, applicable regulations, and the U.S. Food and Drug Administration (FDA) current good manufacturing practices (CGMP).

The system owner is responsible for compliance with CGMP. Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 210-211 prohibits the adulteration of drugs [1].[1] Introducing a drug product into a system that has not been installed in accordance with CGMP will adulterate the product. The supplier of the CMG is responsible for ensuring that the system has been installed in compliance with CGMP prior to first filling of the system. Supplier and contractor personnel that work on supplier-owned equipment shall be able to provide documentation that demonstrates compliance with this standard.

2 Scope

This standard provides the minimum requirements for the design, installation, maintenance, testing, and removal of CMG supply systems at health care facilities. For facilities that are solely intended for use in non-human applications (i.e., veterinary or pharmaceutical), the applicability of this standard is to be determined by the CMG system designer, authority having jurisdiction (AHJ), or other related parties based on facility requirements. Strict adherence to CGMP shall be taken into account to prevent adulteration of the CMG.

This standard applies to all new or upgraded CMG supply systems at health care facilities. It provides direction for compliance with the following national regulations and model codes:

- Federal *Food, Drug, and Cosmetic Act* [2];
- Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 210 to 211 [1];
- NFPA 55, *Compressed Gases and Cryogenic Fluids Code* [3]; and
- NFPA 99, *Health Care Facilities Code* [4].

Section 5 covers the scope of these regulations and their applicability to CMG supply systems. This standard captures the requirements from these codes along with best practices to provide a comprehensive publication for the process of designing, locating, installing, commissioning, maintaining, testing, removing, and documenting work on a medical gas supply system.

In an upgrade, the complete system shall be modified to comply with current standards. Failure of individual components may not invoke a full system upgrade. An exception is replacing piping or control assemblies that do not include the replacement or relocation of the bulk liquid storage vessel(s) may not invoke the foundation requirements in 8.2.

This standard does not apply to:

- piped distribution systems including source valve requirements;

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

- manufacture of assemblies such as pressure control manifolds that are manufactured in a supplier's shop and qualified for medical gas service in accordance with the CMG supply system installer's policies;
- manufacturing plants or other establishments operated by the supplier or the supplier's agent for the purpose of storing and refilling portable containers, trailers, mobile supply trucks, or tank cars with medical gases;
- nonhealth care facilities such as laboratories, pharmaceutical, or biotechnology facilities;
- medical vacuum systems; or
- supply systems that generate CMG on-site.

3 Definitions

For the purpose of this standard, 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.

3.2 Technical definitions

3.2.1 Argon
Inert gas used as a purge medium during the fabrication of welded stainless steel piping assemblies.

3.2.2 Authority having jurisdiction (AHJ)
Organization, office, or individual responsible for enforcing the requirements of a code or standard or responsible for approving equipment, materials, installations, or procedures.

NOTE—There may be multiple AHJs with various levels of responsibilities and authority.

3.2.3 Brazer
Person with documented proficiency in the silver brazing procedures used to join pipe and tubing during the installation of a CMG supply system.

3.2.4 Bulk cryogenic fluid central supply system
Cryogenic fluid central supply system with a storage capacity greater than 566 m^3 (20 000 scf).

3.2.5 Certified
Container or system whose content is manufactured, tested, and in compliance with applicable standards, for example, *United States Pharmacopoeia–National Formulary* (*USP–NF*) or supplier standards [5].

3.2.6 Clean for oxygen service
System or component of a system that is specifically cleaned, inspected, labeled, and packaged for use with oxygen.