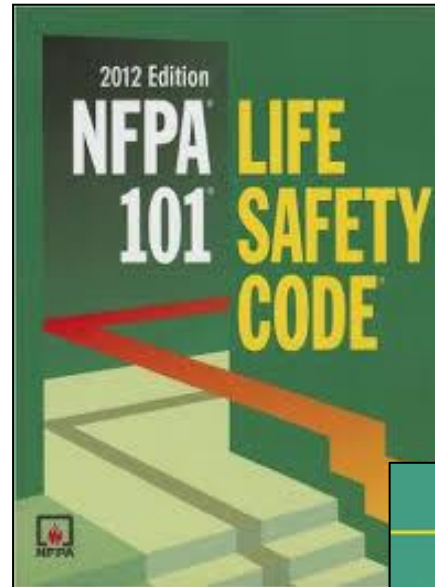


VSHE Central District Meeting

Community Memorial Hospital
South Hill, VA

January 26, 2017

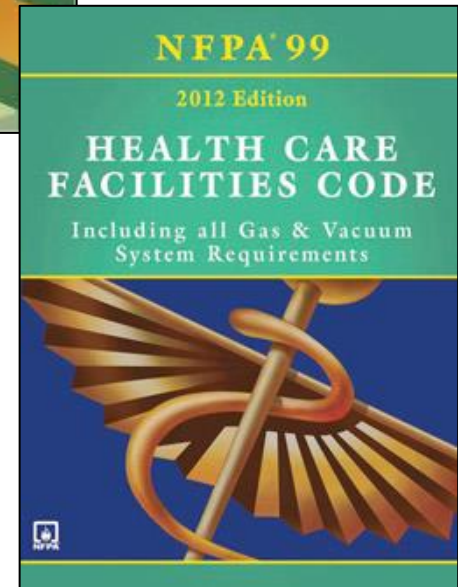


MEDICAL GAS SYSTEMS CODE UPDATES

NFPA 99 HEALTH CARE FACILITIES CODE, 2012 EDITION

PRESENTED BY:

Luke Miller
Praxair PDI Hospital Services
Raleigh, NC



DISCLAIMER

All comments and opinions today are mine alone, based on my personal experience with medical gas systems and my understanding and interpretation of various code requirements.

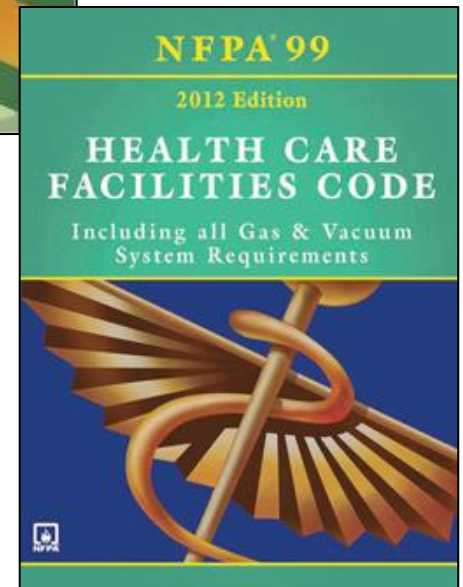
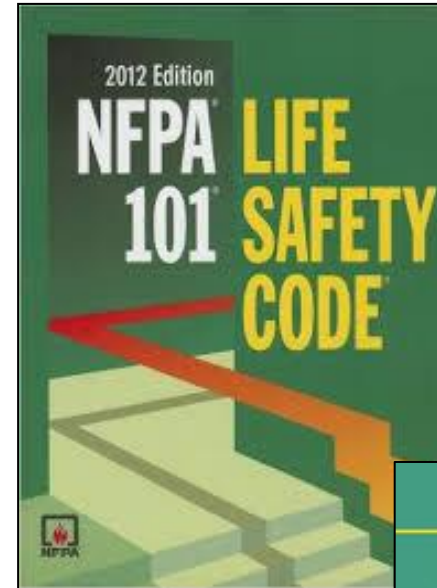
None of my comments have been reviewed by the National Fire Protection Association or any Authorities Having Jurisdiction, and should not be relied upon as a substitute for, or without reference to, codes, standards and/or published safety guidelines.

- With Praxair since 2008
- B.S. Industrial Engineering, NC State University, 2001
- Credentialed Medical Gas Verifier (MGPHO)
- ASSE 6030 Medical Gas Verifier (NITC)
- ASSE 6020 Medical Gas Inspector (NITC)

- For today, CMS is *the* AHJ
 - Other AHJs to consider

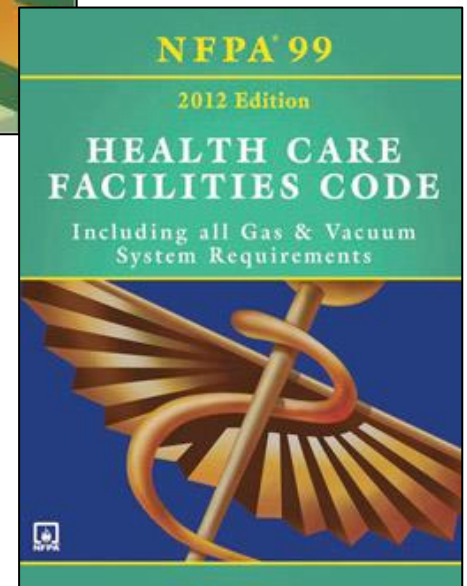
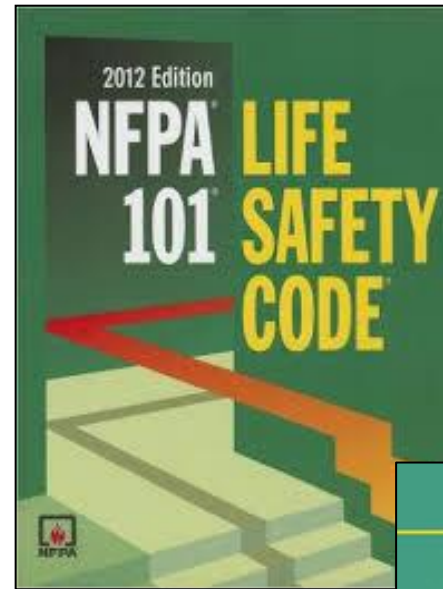
- CMS has adopted *NFPA 101 Life Safety Code, 2012 Edition*
 - Effective July 5, 2016
 - Surveying November 1, 2016
 - Requires compliance with NFPA 99, 2012
 - NFPA 99, 2012 now essentially law

- NFPA 99 references:
 - NFPA 55, *Compressed Gases and Cryogenics Fluids Code*
 - NFPA 70, *National Electric Code*
 - ASSE, ASME, ASTM, CGA, et al.

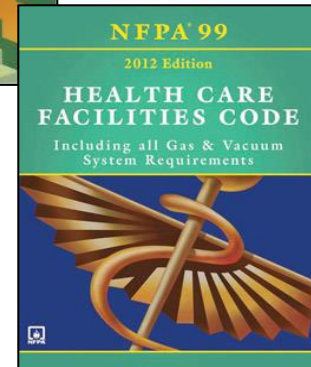
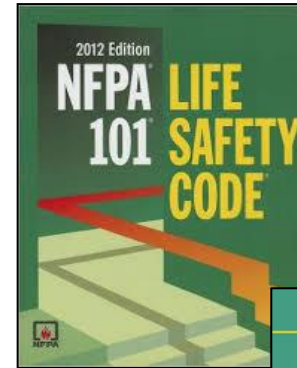


Today's Scope

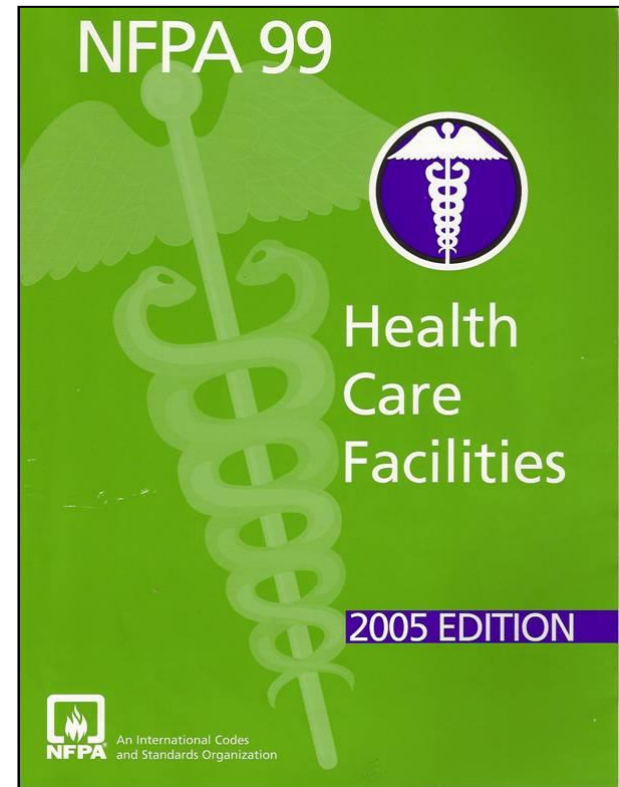
- Medical gas & vacuum systems only
 - No Chapters 6-11 (Electrical Systems, IT, Plumbing, HVAC, Electrical Equipment, Gas Equipment)
 - Major changes to these chapters worth studying
 - Medgas requirements reference these
- Focus on major changes
 - Structure
 - Applicability
 - Chapters 3-5 (Medgas chapters)
 - Not exhaustive
 - Hundreds of changes, many minor



- Previously an occupancy-based standard
 - Levels were based on perception of patient population
- Now a risk-based code
 - Same status as NFPA 70, NFPA 101
 - Can now be adopted *individually* as law
- Reflects how health care is delivered
 - Categories consider risk based on types of procedures performed
- Risk Assessment
 - Main theme throughout
 - Burden now on Facility
 - Exposure now on Facility
- Increased focus on existing facility
 - Previously an installation document
 - Maintenance & Inspection programs



- Eliminated entirely: “Occupancy” Chapters 12-20
 - Eliminated Decision Trees to determine Levels
 - Other chapters deleted: Lab Requirements, Manufacturer’s Requirements, Annex A-E outdated technology
- Medical Gas Chapters
 - Complete overhaul
 - Chapter 1 (Administration)
 - Chapter 3 (Definitions)
 - Chapter 4 (Fundamentals)
 - Chapter 5 (Gas and Vacuum Systems)
 - Ventilation requirements moved to Chapter 9 (HVAC)
 - Bulk requirements moved to or reference NFPA 55
- NPFA 99C no longer published
 - Chapter 5 can no longer be used stand-alone
 - Must reference entire NFPA 99, other codes, standards



- Facility must now classify different areas
 - First example of risk assessment
 - Now explicit

- Areas
 - Critical Care
 - General Care
 - Basic Care
 - Support
 - Anesthetizing
 - Wet Procedure

- Chapter 3 offers guidance

1.3.4 Patient Care Rooms.

1.3.4.1 The governing body of the facility or its designee shall establish the following areas in accordance with the type of patient care anticipated and with the following definitions of the classification (*see definition of patient care room in Chapter 3*):

- (1) Critical care rooms
- (2) General care rooms
- (3) Basic care rooms
- (4) Support rooms

1.3.4.2 Anesthesia. It shall be the responsibility of the governing body of the health care organization to designate anesthetizing locations.

1.3.4.3 Wet Procedure Locations. It shall be the responsibility of the governing body of the health care organization to designate wet procedure locations.

3.3.138* Patient Care Room. Any room of a health care facility wherein patients are intended to be examined or treated. (MED)

3.3.138.1* Basic Care Room. Room in which the failure of equipment or a system is not likely to cause injury to the patients or caregivers but can cause patient discomfort (Category 3). (MED)

3.3.138.2* Critical Care Room. Room in which failure of equipment or a system is likely to cause major injury or death of patients or caregivers (Category 1). (MED)

3.3.138.3* General Care Room. Room in which failure of equipment or a system is likely to cause minor injury to patients or caregivers (Category 2). (MED)

3.3.138.4* Support Room. Room in which failure of equipment or a system is not likely to have a physical impact on patients or caregivers (Category 4). (MED)

3.3.184* Wet Procedure Locations. The area in a patient care room where a procedure is performed that is normally subject to wet conditions while patients are present, including standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff. (FUN)

3.3.9* Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of general anesthesia. (MED)

3.3.138* Patient Care Room. Any room of a health care facility wherein patients are intended to be examined or treated. (MED)

3.3.138.1* Basic Care Room. Room in which the failure of equipment or a system is **not likely** to cause injury to the patients or caregivers but can cause patient discomfort (Category 3). (MED)

3.3.138.2* Critical Care Room. Room in which failure of equipment or a system is **likely** to cause **major injury** or **death** of patients or caregivers (Category 1). (MED)

3.3.138.3* General Care Room. Room in which failure of equipment or a system is **likely** to cause **minor injury** to patients or caregivers (Category 2). (MED)

3.3.138.4* Support Room. Room in which failure of equipment or a system is **not likely** to have a physical impact on patients or caregivers (Category 4). (MED)

3.3.184* Wet Procedure Locations. The area in a patient care room where a procedure is performed that is normally subject to wet conditions while patients are present, including standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff. (FUN)

3.3.9* Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of general anesthesia. (MED)

- **Critical Care**
 - OR
 - PACU
 - ICU
 - L & D
 - Cardiac Cath
- **General Care**
 - Inpatient
 - Dialysis
 - In vitro
 - Procedure
- **Basic Care**
 - Exam
 - Treatment
 - Clinics
- **Support**
 - Anesthesia workroom
 - Sterile Supply
 - Labs
- **Anesthetizing**

3.3.9* Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of general anesthesia. (MED)

3.3.63* General Anesthesia and Levels of Sedation/Analgesia.

3.3.63.1 Deep Sedation/Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (MED)

3.3.63.2 General Anesthesia. A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. (MED)

3.3.63.3 Minimal Sedation (Anxiolysis). A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. (MED)

3.3.63.4 Moderate Sedation/Analgesia (Conscious Sedation). A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. (MED)

- Defining Categories
 - Major shift from conventional thinking
 - Risk-based approach
 - Failure of systems
 - Key word: “likely”
- Category 1
 - Death or major injury
- Category 2
 - Minor injury
- Category 3
 - Discomfort
- Category 4
 - No impact
- Patients or *caregivers*
 - 2015 adds “visitors”

Chapter 4 Fundamentals

4.1* Building System Categories. Building systems in health care facilities shall be designed to meet system Category 1 through Category 4 requirements as detailed in this code.

4.1.1* Category 1. Facility systems in which failure of such equipment or system is likely to cause major injury or death of patients or caregivers shall be designed to meet system Category 1 requirements as defined in this code.

4.1.2* Category 2. Facility systems in which failure of such equipment is likely to cause minor injury to patients or caregivers shall be designed to meet system Category 2 requirements as defined in this code.

4.1.3 Category 3. Facility systems in which failure of such equipment is not likely to cause injury to patients or caregivers, but can cause patient discomfort, shall be designed to meet system Category 3 requirements as defined in this code.

4.1.4 Category 4. Facility systems in which failure of such equipment would have no impact on patient care shall be designed to meet system Category 4 requirements as defined in this code.

- **Determining Category**
 - Guidance on who and how

- **Risk Assessment**
 - Burden on Facility
 - Exposure on Facility

- **Policies & Procedures**
 - Customized
 - Documented

4.2* Risk Assessment. Categories shall be determined by following and documenting a **defined risk assessment procedure**.

A.4.2 Risk assessment should follow procedures such as those outlined in ISO/IEC 31010, *Risk Management—Risk Assessment Techniques*, NFPA 551, *Guide for the Evaluation of Fire Risk Assessments*, *Guide for the Evaluation of Fire Risk Assessments*, SEMI S10- 0307E, *Safety Guideline for Risk Assessment and Risk Evaluation Process*, or other formal process. The results of the assessment procedure should be documented and records retained.

A.6.3.2.2.8.4 In conducting a risk assessment, the health care governing body should consult with all relevant parties, including, but not limited to, clinicians, biomedical engineering staff, and facility safety engineering staff.

■ Applicability

- Major overhaul from NFPA 99, 1999
 - Previously required by CMS
- “Grandfather Clause”
 - Major renovations often impractical, cost-prohibitive
 - All existing conditions not equal
- “Hazard to life”
 - Life safety issues not “grandfathered”
 - Example: master alarms
- Consult AHJ

■ New Facility

- Chapter 5 required in entirety

■ Existing Facility

- Maintenance
- Inspections
- Qualifications

■ New & Existing Facilities

- Record Keeping

5.1.1.4 An existing system that is not in strict compliance with the provisions of this code shall be permitted to be continued in use as long as the authority having jurisdiction has determined that such use does not constitute a distinct hazard to life.

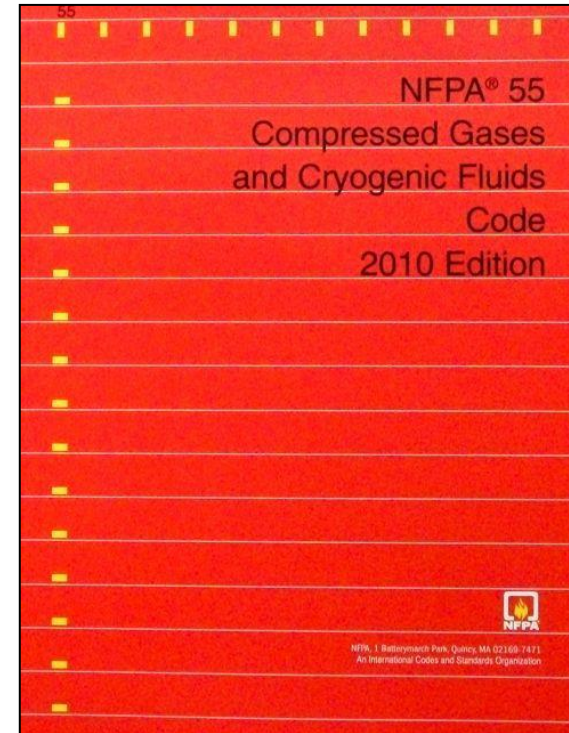
5.1.1.5 Subsection 5.1.2 through 5.1.12.3.14.5 and 5.1.14.4.2 shall apply to new health care facilities or facilities making changes that alter the piping.

5.1.1.6 Paragraph 5.1.14.4.3 through 5.1.14.4.9 and 5.1.13 through 5.1.15 shall apply to existing health care facilities.

5.1.1.7 Paragraph 5.1.14.3 and 5.1.14.4.1 shall apply to new and existing health care facilities.

■ Contains core requirements

- Cylinder storage
 - References Chapter 9 (HVAC)
- Source equipment
 - Bulk references NFPA 55
- Pipeline components
- Performance
- Design
- Installation
- Verifications
- Inspections
- Maintenance



(A few) Notable Changes

- No wooden racks in cylinder storage
- Minimum temperature for N₂O and CO₂ storage defers to manufacturer
- Defines “Bulk System” at 20,000 cuft (regardless of gas)
- No cylinder storage with motor-driven
- 3 ft clearance around EOSC
- 25 ft Medical Air intake location from various exhaust and vent points
- Allows for communication technology other than “wire”
- Various installation techniques
 - Prohibits introducing copper shavings into pipe
- Medical Air Dew Point local/master alarm 35°F
 - Dryer package must still maintain 32°F
- Installer qualifications
 - “Individual” must have ASSE 6010
- Outdoor enclosures two egress gates
 - Escape in emergency
- AHJ must witness 24-hour standing pressure tests
 - Impractical to require/enforce
- Vacuum exhaust away from “places of public assembly”
 - Consolidate AIA/FGI requirement
- WAGD and oil vacuum pumps more defined limits on oxidizers
- Requires WAGD inlet in anesthetizing locations where N₂O may be not piped
- Alarm switches and sensors must be on **removable**, gas-specific demand checks

■ Permitted locations of med gases

- Piped into areas “used under direction of licensed medical professionals”
 - Direct respiration
 - Clinical applications
 - Medical device applications
 - Power for medical devices
 - Calibration of above
- Example of prohibited
 - Workstation blow down
- Applies to Support Gases
 - Nitrogen
 - Instrument Air

5.1.3.5.2 Permitted Locations for Medical Gases.

Central supply systems and medical gas outlets for oxygen, medical air, nitrous oxide, carbon dioxide, and all other patient medical gases shall be piped only into areas where the gases will be used under the direction of licensed medical professionals for purposes congruent with the following:

- (1) Direct respiration by patients
- (2) Clinical application of the gas to a patient, such as the use of an insufflator to inject carbon dioxide into patient body cavities during laparoscopic surgery and carbon dioxide used to purge heart-lung machine blood flow ways
- (3) Medical device applications directly related to respiration
- (4) Power for medical devices used directly on patients
- (5) Calibration of medical devices intended for (1) through (4)

5.1.3.5.3 Support Gases. Central supply systems for support gases shall not be piped to, or used for, any purpose except medical support application.

- Relocated to Chapter 9 (HVAC)
 - Cylinder storage and transfilling
 - References NFPA 55
 - Waste Gas
 - Reference Chapter 5
 - Active or passive systems
 - Natural or mechanical ventilation
 - Eliminated “3,000 cuft connected and in storage”
 - Practical design
 - Allows more flexibility
 - Accounts for small leaks only
 - Recommend O2 concentration alarm

9.3.8 Waste Gas.

9.3.8.1 Removal of excess anesthetic gases from the anesthesia circuit shall be accomplished by waste anesthetic gas disposal (WAGD), as described in Chapter 5, or by an active or passive scavenging ventilation system.

5.1.5.16 WAGD networks shall provide a WAGD inlet in all locations where nitrous oxide or halogenated anesthetic gas is intended to be administered.

9.3.7.5 Indoor storage or manifold areas and storage or manifold buildings for medical gases and cryogenic fluids shall be provided with **natural** ventilation **or mechanical** exhaust ventilation in accordance with 9.3.7.5.1 through 9.3.7.8.

9.3.7.5.2 Natural Ventilation.

9.3.7.5.2.1 Natural ventilation shall consist of two nonclosable louvered openings, each having an aggregate free opening area of at least 155 cm²/35 L (24 in.²/1000 ft³) of the fluid designed to be stored in the space and in no case less than 465 cm² (72 in.²).

9.3.7.5.2.2 One opening shall be located within 30 cm (1 ft) of the floor, and one shall be located within 30 cm (1 ft) of the ceiling.

9.3.7.5.2.3 The openings shall be located to ensure cross ventilation.

9.3.7.5.2.4 Natural ventilation openings shall be directly to the outside atmosphere without ductwork.

9.3.7.5.2.5 Mechanical ventilation shall be provided if natural ventilation requirements cannot be met.

9.3.7.5.3 Mechanical Ventilation.

9.3.7.5.3.1 Mechanical exhaust to maintain a negative pressure in the space shall be provided continuously, unless an alternative design is approved by the authority having jurisdiction.

9.3.7.5.3.2 Mechanical exhaust shall be at a rate of 1 L/sec of airflow for each 300 L (1 cfm per 5 ft³ of fluid) designed to be stored in the space and not less than 24 L/sec (50 cfm) nor more than 235 L/sec (500 cfm).

9.3.7.5.3.3 Mechanical exhaust inlets shall be unobstructed and shall draw air from within 300 mm (1 ft) of the floor and adjacent to the cylinder or containers.

9.3.7.5.3.4 Mechanical exhaust air fans shall be supplied with electrical power from the essential electrical system.

9.3.7.6 Discharge from the natural and mechanical ventilation systems shall be sited by a minimum separation distance in accordance with NFPA 55, *Compressed Gases and Cryogenic Fluids Code*.

9.3.7.7 A storage room shall maintain a temperature not greater than 52°C (125°F).

9.3.7.8 A transfer or manifold room shall maintain a temperature not greater than 52°C (125°F) and not less than -7°C (20°F).

■ Zone Valves

- 1999-2005 major re-write
- 2012 adds a new provision
- (Poor) attempt to clarify “intervening wall” gray area

NFPA 99, 2005:

5.1.4.8 Zone Valve. All station outlets/inlets shall be supplied through a zone valve as follows:

- (1) The zone valve shall be placed such that a wall intervenes between the valve and outlets/inlets that it controls.
- (2) The zone valve shall serve only outlets/inlets located on that same story.

NFPA 99, 2012:

5.1.4.8 Zone Valves. All station outlets/inlets shall be supplied through a zone valve as follows:

- (1) The zone valve shall be placed such that a wall intervenes between the valve and outlets/inlets that it controls.
- (2) The zone valve shall serve only outlets/inlets located on that same story.
- (3) The zone valve shall not be located in a room with station outlets/inlets that it controls.

■ Maintenance Programs

- Significant focus
- Source to patient-use
- Now explicit
- Conventional thinking was C&D caused issues
- Poor maintenance is major concern
- Routine maintenance program
 - Customized
 - Documented
 - Risk assessment
 - OEM recommendations
 - AHJ requirements

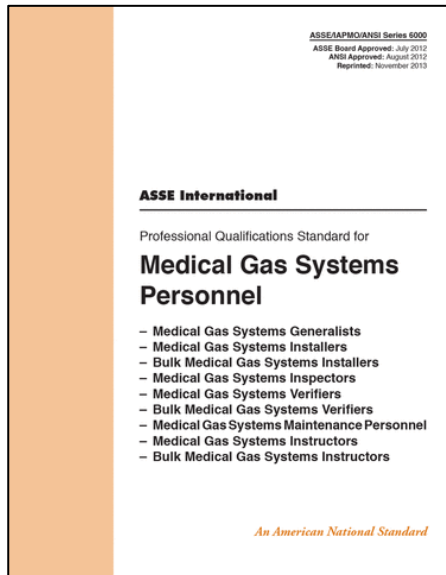
5.1.14.2.2.1 Inventories. Inventories of medical gas...systems shall include at least all source subsystems, control valves, alarms, manufactured assemblies containing patient gases, and outlets.

5.1.14.2.2.4 Maintenance Schedules. Scheduled maintenance for equipment and procedures shall be established through the risk assessment of the facility and developed with consideration of the original equipment manufacturer recommendations and other recommendations as required by the authority having jurisdiction.

5.1.15 Category 1 Maintenance. Facilities shall have a routine maintenance program for their piped medical gas and vacuum systems

■ Maintenance Personnel Qualifications

- Applies in-house or external
 - 2015 adds “documented” and “or contracted”
- In-house training and certification, equipment-specific
- ASSE 6040
- ASSE 6030



5.1.14.2.2.5 Qualifications. Persons maintaining these systems shall be qualified to perform these operations. Appropriate qualifications shall be demonstrated by any of the following:

- (1) Training and certification through the health care facility by which such persons are employed to work with specific equipment as installed in that facility
- (2) Credentialing to the requirements of ASSE 6040, *Professional Qualification Standard for Medical Gas Maintenance Personnel*
- (3) Credentialing to the requirements of ASSE 6030, *Professional Qualification Standard for Medical Gas Systems Verifiers*

- Minimum requirements only
- Due diligence
 - All medgas personnel not equal

■ Inspection Programs

- Extension of routine maintenance program
 - Risk assessment
 - OEM recommendations
 - AHJ requirements
- Permanent records
- Intentionally vague on frequency
 - “Annual” for source equipment
 - “Periodic” for pipeline components
 - 18-months for booms, pendants
- Develop customized program
- Due diligence
- Renovations: verification downstream

5.1.14.2.2.2 Inspection Schedules. Scheduled inspections for equipment and procedures shall be established through the risk assessment of the facility and developed with consideration of the original equipment manufacturer recommendations and other recommendations as required by the authority having jurisdiction.

5.1.14.4.3 An annual review of bulk system capacity shall be conducted to ensure the source system has sufficient capacity.

5.1.14.4.4 Central supply systems for nonflammable medical gases shall conform to the following:

(1) They shall be inspected annually.

(2) They shall be maintained by a qualified representative of the equipment owner.

(3) A record of the annual inspection shall be available for review by the authority having jurisdiction.

5.1.14.4.5 A periodic testing procedure for nonflammable medical gas and vacuum and related alarm systems shall be implemented.

5.1.14.2.3.2 Manufactured Assemblies Employing Flexible Connection(s) Between the User Terminal and the Piping System.

(A) Nonstationary booms and articulating assemblies, other than head walls utilizing flexible connectors, shall be tested for leaks, per manufacturer’s recommendations, every 18 months or at a duration as determined by a risk assessment.

5.1.14.4.6 Whenever modifications are made that breach the pipeline, any necessary installer and verification test specified in 5.1.12 shall be conducted on the downstream portions of the medical gas piping system.

5.1.14.2.3 Inspection and Testing Operations.

5.1.14.2.3.1 General. The elements in 5.1.14.2.2 through 5.1.15 shall be inspected or tested as part of the maintenance program as follows:

- (1)*Medical air source
- (2)*Medical vacuum source
- (3) WAGD source
- (4)*Instrument air source
- (5)*Manifold sources
- (6) Bulk cryogenic liquid source
- (7) Final line regulation for all positive pressure systems
- (8)*Valves
- (9)*Alarms and warning systems
- (10) Alarms and warning systems, as follows:
- (11)*Station outlets/inlets

5.1.14.4.7 Procedures, as specified, shall be established for the following:

- (1) Maintenance program for the medical air compressor supply system in accordance with the manufacturer's recommendations
- (2) Facility testing and calibration procedure that ensures carbon monoxide monitors are calibrated at least annually or more often if recommended by the manufacturer
- (3) Maintenance program for both the medical–surgical vacuum piping system and the secondary equipment attached to medical surgical vacuum station inlets to ensure the continued good performance of the entire medical–surgical vacuum system
- (4) Maintenance program for the WAGD system to ensure Performance

5.1.14.4.8 Audible and visual alarm indicators shall meet the following requirements:

- (1) They shall be periodically tested to determine that they are functioning properly.
- (2) Records of the test shall be maintained until the next test is performed.

5.1.14.4.9 Medical–surgical vacuum station inlet terminal performance, as required in 5.1.12.3.10.4, shall be tested as follows:

- (1) On a regular preventive maintenance schedule as determined by the facility maintenance staff
- (2) Based on flow of free air (NI/min or SCFM) into a station inlet while simultaneously checking the vacuum level

- Much-improved guide for safety
 - Approach medgas systems same as other Life Safety Systems
- Not perfect
 - Much of the guidance remains vague
 - Still gray areas
 - Imprecise definitions: “likely,” “discomfort” vs. “minor injury”
 - Often defers to OEM
 - Ultimately, defers to Facility
 - Risk assessment
 - Outdated by time CMS adopted
 - 2015 current edition
 - Clean-up, not overhaul
 - Adopted by some AHJs
 - 2018 next edition
 - Major overhaul



■ Proper application key

- Minimum requirements only
- Simplify and standardize design
- Allows for flexibility
- Update C&D specs to reference 2012
- Reduce costs
 - Example 1: area alarms locations
 - Example 2: anesthetizing area alarms
 - Example 3: WAGD

5.1.3.8.1.1 WAGD shall be permitted to be produced through the medical–surgical vacuum source, by a dedicated producer, or by venturi.

5.1.3.8.1.2 If WAGD is produced by the medical–surgical vacuum source, the following shall apply:

- (1) The medical–surgical vacuum source shall comply with 5.1.3.7.
- (2) The total concentration of oxidizers (oxygen and nitrous oxide) shall be maintained below 23.6 percent, or the vacuum pump shall comply with 5.1.3.8.2.1.
- (3) The medical–surgical vacuum source shall be sized to accommodate the additional volume.

5.1.9.3* Area Alarms. Area alarm panels shall be provided to monitor all medical gas, medical–surgical vacuum, and piped WAGD systems supplying the following:

- (1) Anesthetizing locations where moderate sedation, deep sedation, or general anesthesia is administered
- (2)*Critical care areas

5.1.9.3.4 Alarm sensors for area alarms shall be located as follows:

- (1)*Critical care areas shall have the alarm sensors installed on the patient or use side of each individual zone valve box assemblies.
- (2)*Anesthetizing locations where moderate sedation, deep sedation, or general anesthesia is administered shall have the **sensors installed either on the source side** of any of the individual room zone valve box assemblies or on the patient or use side of each of the individual zone valve box assemblies.

Thank you!

