MEMORANDUM

TO: NFPA Technical Committee on Medical Equipment

FROM: Jeanne Moreau-Correia

DATE: March 2, 2010

SUBJECT: NFPA 99 A11 ROP Letter Ballot

The ROP letter ballot for NFPA 99 HEA-MED is attached. The ballot is for formally voting on whether or not you concur with the committee’s actions on the proposals. Reasons must accompany all negative and abstention ballots.

Please do not vote negatively because of editorial errors. However, please bring such errors to my attention for action.

Please complete and return your ballot as soon as possible but no later than Monday, March 15, 2010. As noted on the ballot form, please submit the ballot to Jeanne Moreau-Correia, e-mail to jmoreaucorreia@nfpa.org or fax to 617-984-7110.

The return of ballots is required by the Regulations Governing Committee Projects.

Attachment: Proposals
Add new text as follows:

Electromagnetic compatibility, or EMC means that a device is compatible with (i.e., no interference is caused by) its electromagnetic (EM) environment and it does not emit levels of EM energy that cause electromagnetic interference (EMI) in other devices in the vicinity. A medical device can be vulnerable to EMI if the levels of EM energy in its environment exceed the EM immunity (resistance) to which the device was designed and tested. The different forms of EM energy that can cause EMI are conducted, radiated, and electrostatic discharge (ESD). EMI problems with medical devices can be very complex, not only from the technical standpoint but also from the view of public health issues and solutions.

http://www.fda.gov/cdrh/emc/index.html

Substantiation: Electromagnetic Interference (EMI).

http://www.fda.gov/cdrh/emc-in-hcf.html

Note: Supporting material is available for review at NFPA Headquarters.

Committee Meeting Action: Reject

Committee Statement: The proposal does not specify where the material should go and does not fit the current structure.

Technical Committee on Medical Equipment,

Add new definition to read as follows:

Transfilling. The process of transferring a medical gas in gaseous or liquid state from one container or cylinder to another container or cylinder (MED).

This definition was needed to clarify the difference between transfilling and transferring. Transferring is a broader term and transfilling is more specific with gases.

Committee Meeting Action: Accept

Jan Ehrenwerth, Yale University School of Medicine

Revise text to read as follows:

Anesthetic. As used in this standard, applies to any intravenous, intramuscular, or inhalation agent used to produce relative analgesia: minimal sedation (anxiolysis), moderate sedation/analgesia (conscious sedation), deep sedation/analgesia, or general anesthesia. (MED)

Relative analgesia is an old and outdated terminology. The continuum of depth of sedation is the current terminology. An Anesthetic is more than just inhalation agents.

This is not original material; its reference/source is as follows:


Committee Meeting Action: Accept in Principle

Revise to read as follows:

3.3.8 Anesthetic. As used in this code, applies to any inhalational agent used to produce sedation, analgesia or general anesthesia. (MED)

Committee Statement: This document does not address intramuscular anesthesia.
3.3.8 Anesthetic. As used in this standard, applies to any intravenous, intramuscular, or inhalation agent used to produce
relative analgesia, minimal sedation (anxiolysis), moderate sedation/analgesia (conscious sedation), deep
sedation/analgesia, or general anesthesia. (GAS)

Substantiation: Relative analgesia is an old and outdated terminology. The continuum of depth of sedation is the
current terminology. An Anesthetic is more than just inhalation agents.

Committee Meeting Action: Accept in Principle

Committee Statement: This document does not address intramuscular anesthesia.

3.3.9* Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of
inhalational anesthetic agents.

Substantiation: The old definition of anesthetic agents and anesthetizing location is not accurate. It has been revised
to reflect current terminology. Relative analgesia is not current terminology.

Committee Meeting Action: Accept in Principle

Committee Statement: The use of intramuscular is not used in this standard. The word moderate is too limiting and
was deleted.
3.3.9* Anesthetizing Location. Any area of a facility that has been designated to be used for the administration of nonflammable inhalation, intravenous or intramuscular anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia. (See definition of Relative Analgesia.) (GAS) general anesthesia, minimal, moderate, or deep sedation/analgesia. (See definition of Continuum of Depth of Sedation.)

Substantiation: The old definition of anesthetic agents and anesthetizing location is not accurate. It has been revised to reflect current terminology. Relative analgesia is not current terminology.

This is not original material; its reference/source is as follows:
Committee Meeting Action: Accept in Principle
Committee Statement: The use of intramuscular is not used in this standard. The word moderate is too limiting and was deleted.

3.3.23* Combustion. A chemical process (such as oxidation) accompanied by the rapid evolution of heat and light. A chemical process of oxidation that occurs at a rate fast enough to produce heat and usually light in the form of either a glow or flame (NFPA 5000).
A.3.3.23 Combustion. Combustion is not limited to a chemical reaction always involving oxygen. Certain metals, such as calcium and aluminum, will burn in nitrogen; nitrous oxide will support the combustion of phosphorus and carbon; and so on. However, this document deals with the more common process of fuels burning in air.
Substantiation: The preferred definition of the term “combustion” within the NFPA system is the one from NFPA 5000, Building Construction and Safety Code.

The Glossary of Terms Advisory committee recommends that the definition from NFPA 5000 be adopted by NFPA 99, so as to obtain consistency of terms. It is also recommended that the annex note be retained within NFPA 99 as it helps specific use within NFPA 99.
I am the chairman of the NFPA Advisory Committee on the Glossary on Terminology. The committee was created by NFPA Standards Council to provide consistency in terminology throughout the NFPA documents. The committee has not had time to review all of my recommendations on definitions of terms. Therefore, this proposal is being submitted in my own name only.

Committee Meeting Action: Reject
Committee Statement: This definition is not used in the gas chapter and the proposal should be addressed by the Fundamentals Committee.
3.3.24 Combustion Products. The gases, volatilized liquids and solids, particulate matter, and ash generated by combustion.

The preferred definition of the term “combustion products” within the NFPA system is the one from NFPA 54, National Fuel Gas Code. The definition reads as follows:

3.3.21 Combustion Products. Constituents resulting from the combustion of a fuel with the oxygen of the air, including the inert but excluding excess air.

The Glossary of Terms Advisory committee recommends that the definition from NFPA 99 be retained as the NFPA 54 definition is too limiting for general use, and specifically for NFPA 99 use.

I am the chairman of the NFPA Advisory Committee on the Glossary on Terminology. The committee was created by NFPA Standards Council to provide consistency in terminology throughout the NFPA documents. The committee has not had time to review all of my recommendations on definitions of terms. Therefore, this proposal is being submitted in my own name only.

Committee Meeting Action: Reject
Committee Statement: See Committee Action on Committee Proposal 99-36 (Log #358).
3.3.131* Oxygen. An element that, at atmospheric temperatures and pressures, exists as a colorless, odorless, tasteless gas.

3.3.131* A chemical element that, at normal atmospheric temperatures and pressures, exists as a colorless, odorless, and tasteless gas and comprises about 21 percent by volume of the earth's atmosphere.

3.3.131.1 Gaseous Oxygen. A colorless, odorless, and tasteless gas; also, the physical state of the element at atmospheric temperature and pressure.

3.3.131.1. Gaseous oxygen. A colorless, odorless, tasteless, and non toxic gas, comprising about 21 percent of normal air by volume, that is about 10 percent heavier than air; also the physical state of the element at atmospheric temperature and pressure.

A.3.3.131 Oxygen. Its outstanding property is its ability to sustain life and to support combustion. Although oxygen is nonflammable, materials that burn in air will burn much more vigorously and create higher temperatures in oxygen or in oxygen-enriched atmospheres.

Substantiation: The existing definition of oxygen in NFPA 99 is different from the NFPA preferred definition, contained in NFPA 53. The NFPA 53 definition is broader and more complete and it is recommended that the NFPA 53 definition of oxygen be adopted.

With regard to gaseous oxygen, it is recommended that the definition from NFPA 99 be amended but that the NFPA preferred definition, contained in NFPA 410, not be adopted but that both be combined to obtain a more complete definition. The NFPA 410 definition reads:

3.3.16 Gaseous Oxygen. (preferred) NFPA 410-2004
A colorless, tasteless, and nontoxic gas, comprising about 21 percent of normal air by volume, that is about 10 percent heavier than air.

It might also be worth noting the annex note from NFPA 410, which reads as follows, as a potential addition to the gaseous oxygen annex note in NFPA 99:

A.3.3.16 Gaseous Oxygen. Above its critical temperature of -118°C (-180.4°F), oxygen can exist only as a gas regardless of the pressure exerted on it.

I am the chairman of the NFPA Advisory Committee on the Glossary on Terminology. The committee was created by NFPA Standards Council to provide consistency in terminology throughout the NFPA documents. The committee has not had time to review all of my recommendations on definitions of terms. Therefore, this proposal is being submitted in my own name only.

Committee Meeting Action: Accept
Technical Committee on Medical Equipment,

99-66 Log #CP901 HEA-MED
(3.3.139 Patient-Care-Related Electrical Equipment)

Final Action: Accept

Submitter: Technical Committee on Medical Equipment,

Recommendation: Revise the definition to read as follows:

Patient-Care-Related Electrical Equipment. Electrical equipment that is intended to be used for diagnostic, therapeutic, or monitoring purposes in a patient care vicinity.

Substantiation: Appliance is a misleading term.

Committee Meeting Action: Accept

Jan Ehrenwerth, Yale University School of Medicine

99-67 Log #392 HEA-MED
(3.3.158 Relative Analgesia)

Final Action: Accept in Principle

Submitter: Jan Ehrenwerth, Yale University School of Medicine

Recommendation: Revise text to read as follows:

Relative Analgesia - A state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness (conscious sedation). (SAS) Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia. Minimal Sedation (Anxolyis) - 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. 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 patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. 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. 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. It should be noted that these are not static conditions. Minimal sedation can easily become moderate sedation, and moderate sedation can progress to deep sedation or general anesthesia.

Substantiation: Relative analgesia is not currently used terminology. The current definitions have been adopted by the American Society of Anesthesiologists and should be used in this document.

This is not original material; its reference/source is as follows:

Committee Meeting Action: Accept in Principle

Replace Relative Analgesia with Moderate Sedation to read as follows:

Moderate Sedation (Conscious Sedation) - A drug-induced depression of consciousness during which patients respond to verbal commands, either alone or accompanied by light tactile stimulation.

Committee Statement: This is meant as a replacement of the original term. The other definitions are not relative to replacing the original term.
Relative Analgesia. A state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness (conscious sedation). (GAS)

Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

- **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. **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 patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

**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. **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. It should be noted that these are not static conditions. Minimal sedation can easily become moderate sedation, and moderate sedation can progress to deep sedation or general anesthesia.

Substantiation: Relative analgesia is not currently used terminology. The current definitions have been adopted by the American Society of Anesthesiologists and should be used in this document. This is not original material; its reference/source is as follows:


Committee Meeting Action: Accept in Principle in Part

Replace Relative Analgesia with Moderate Sedation to read as follows:

**Moderate Sedation (Conscious Sedation)** - A drug-induced depression of consciousness during which patients respond to verbal commands, either alone or accompanied by light tactile stimulation.

Committee Statement: This is meant as a replacement of the original term. The other definitions are not relative to replacing the original term.

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Submitter: Burton R. Klein, Burton Klein Associates

**Recommendation:**

1. Delete 5.1.13, 5.2.13 and 5.3.13 from Chapter 5.
2. Delete Section 9.8 from Chapter 9.
3. Create a new Chapter 6 titled, "Piped Gas and Vacuum System Requirements for Existing Facilities."
4. Insert 5.1.13, 5.2.13, 5.3.13, and Section 9.8 into new Chapter 6, renumbered as Sections 6.1, 6.2, 6.3, and 6.4 respectively.
5. Revise title of Chapter 5 to "Piped Gas and Vacuum Requirements for New Facilities."
6. Renumber current Chapters 6 to 21 as 7 to 22, respectively.

Substantiation: Make it easier for users and enforcers of document to see which requirements are applicable to new facilities, and which are applicable to existing facilities. (In the similar fashion to arrangement in NFPA 101.)

Committee Meeting Action: Accept in Part

The committee accepts part 2 only.

Committee Statement: The remainder of the proposal is not in the jurisdiction of the MED committee.
Central supply systems for oxygen, medical air, nitrous oxide, carbon dioxide, and all other patient medical gases shall not be piped to, or used for, any purpose except patient care application or in the operation of USFDA registered medical devices providing this device works at a pressure lower than the oxygen pressure piping network. Medical air shall be used only in the application of human respiration, and calibration of medical devices for respiratory application.

Substantiation: The TSO₃ 125L Ozone Sterilizer is a Class II medical device registered with and cleared to market by the USFDA. In the device application (510k) submitted to the USFDA, TSO₃ identified oxygen USP as the grade of oxygen required for the proper operation of this class II medical device. The oxygen source for this medical device can be provided from individual high pressure oxygen cylinders or from the oxygen central supply system. The handling and use of high pressure steel cylinders has inherent hazards even when they are handled and used in accordance with industry guidelines. Some of these hazards are: movement of the heavy steel cylinders, accidental release of the high pressure gas (+2000 psig), fire and explosion due to the accidental contamination of connections during change out. These hazards do not exist when oxygen is supplied to the TSO₃ 125L Ozone Sterilizer from a central supply system. There is no constant movement of heavy steel cylinders, the pressure from the central supply system is low (55 psig or less) and there is no potential for contamination due to the continuous connection or disconnection of the oxygen supply since the pressure is even lowered at 20 psig at the inlet of the unit, 2 psig in the ozone generator and under atmospheric pressure in the sterilization chamber.

Committee Meeting Action: Accept in Principle
Add new section as follows:

9.5.3.3 Sterilizers. Equipment using medical grade oxygen from the piped distribution system shall meet the following requirements:
1) Not be permanently attached to the piped distribution system,
2) Be connected to the piped distribution system using a wall outlet and a flexible hose,
3) Be a medical device which has been listed with the United States Food & Drug Administration,
4) It operate at or below 5 psig (34.5 kPa).

Committee Statement: This was rewritten to fit into the format of the chapter.
Technical Committee on Medical Equipment, 

Recommendation: Revise Chapter 8 and renumber as Chapter 10 as follows:

Chapter 10 Electrical Equipment

10.1* Applicability.
10.1.1 This chapter shall cover the performance, maintenance, and testing of electrical equipment used within health care facilities.
10.1.2 Experimental or research apparatus built to order or under development shall be used under qualified supervision and shall have a degree of safety equivalent to that described herein or that has been deemed acceptable by the facility.

10.2 Performance Criteria and Testing for Patient-Care-Related Electrical Appliances and Equipment.
10.2.1 Permanently Connected — Fixed Equipment. Patient-connected electric appliances shall be grounded to the equipment grounding bus in the distribution panel by an insulated grounding conductor run with the power conductors.
10.2.2 Cord- and Plug-Connected — Portable Equipment.
10.2.2.1 Grounding of Appliances.
10.2.2.1.1 All cord-connected electrically powered appliances that are not double insulated and are used in the patient care vicinity shall be provided with a three-wire power cord and a three-pin grounding-type plug.
10.2.2.1.2 Double-insulated appliances shall be permitted to have two conductor cords and shall be rated as Class II devices.
10.2.2.2 Attachment Plugs. Attachment plugs listed for the purpose shall be used on all cord-connected appliances.
10.2.2.3 Construction and Use. The attachment plug shall be a two-pole, three-wire grounding type.
10.2.2.3.1 Appliances supplied by other than 120 V single-phase systems shall use the grounding-type plug (cap) appropriate for the particular power system.
10.2.2.3.2 The grounding prong of the plug shall be the first to be connected to and the last to be disconnected from the receptacle.
10.2.2.3.3 If screw terminals are used, the stranded conductor shall be twisted to prevent stray strands, but the bundle shall not be tinned after twisting.
10.2.2.3.4 If the conductor is not twisted, it shall be attached by an approved terminal lug.
10.2.2.3.5 The power-cord conductors shall be arranged so that the conductors are not under tension in the plug.
10.2.2.3.6 The grounding conductor shall be the last one to disconnect when a failure of the plug's strain relief allows the energized conductors to be disrupted.
10.2.2.3.7 Strain Relief. Strain relief shall be provided.
10.2.2.3.7.1 The strain relief shall not cause thinning of the conductor insulation.
10.2.2.3.7.2 The strain relief of replaceable plugs shall be capable of being disassembled.
10.2.2.3.7.3 Plugs shall be permitted to be integrally molded onto the cord jacket if the design is listed for the purpose.
10.2.2.3.8 Testing. The wiring of each cord assembly shall be tested for continuity and polarity at the time of manufacture, when assembled into an appliance, and when repaired.
10.2.3 Power Cords.
10.2.3.1 Material and Gauge.
10.2.3.1.1 The flexible cord, including the grounding conductor, shall be of a type suitable for the particular application, listed for use at a voltage equal to or greater than the rated power line voltage of the appliance, and have an ampacity, as given in Table 400.5(A) of NFPA 70, National Electrical Code, equal to or greater than the current rating of the device.
10.2.3.1.2 “Hard Service” (SO, ST, or STO) or “Junior Hard Service” (SJO, SJT, or SJTO) or equivalent listed flexible cord shall be used except where an appliance with a cord of another designation has been listed for the purpose.
10.2.3.2 Grounding Conductor.
10.2.3.2.1 Each electric appliance shall be provided with a grounding conductor in its power cord.
10.2.3.2.2 The grounding conductor shall be no smaller than 18 AWG.
10.2.3.2.3 The grounding conductor of cords longer than 4.6 m (15 ft) shall be no smaller than 16 AWG.
10.2.3.2.4 A grounding conductor in the power cord shall not be required for double-insulated appliances, but a functional ground conductor (functional earth conductor) shall be permitted.
10.2.3.3 Separable Cord Sets.

10.2.3.3.1 A detachable power cord shall be permitted if an accidental disconnection would not present an unacceptable hazard or if a mechanism that reliably prevents inadvertent disconnection is used.

10.2.3.3.2 Separable power cord sets shall be designed so that the grounding conductor is the first to be connected and the last to be disconnected.

10.2.3.3.3 The cord set to the appliance shall be listed for the purpose.

10.2.3.4 Connection to Circuit and Color Codes.

10.2.3.4.1 Power cords, regardless of whether intended for use on grounded or isolated power systems, shall be connected in accordance with the conventions of a grounded system.

10.2.3.4.2 The circuit conductors in the cord shall be connected to the plug and the wiring in the appliance so that any of the following devices, when used in the primary circuit, are connected to the ungrounded conductor:

1. The center contact of an Edison base lampholder
2. A solitary fuseholder
3. A single-pole, overcurrent-protective device
4. Any other single-pole, current-interrupting device

10.2.3.4.3 A second fuseholder or other overcurrent-protective device provided in the appliance shall be permitted to be placed in the grounded side of the line.

10.2.3.7 Cord Strain Relief.

10.2.3.7.1 Cord strain relief shall be provided at the attachment of the power cord to the appliance so that mechanical stress, either pull, twist, or bend, is not transmitted to internal connections.

10.2.3.7.2 A strain relief molded onto the cord shall be bonded to the jacket and shall be of compatible material.

10.2.3.8 Multiple Outlet Connection. Two or more power receptacles supplied by a flexible cord shall be permitted to be used to supply power to plug-connected components of a movable equipment assembly that is rack-, table-, pedestal-, or cart-mounted, provided that all of the following conditions are met:

1. The receptacles are an integral part of the equipment assembly, permanently attached.
2. The sum of the ampacity of all appliances connected to the outlets does not exceed 75 percent of the ampacity of the flexible cord supplying the outlets.
3. The ampacity of the flexible cord is in accordance with NFPA 70, National Electrical Code.
4. The electrical and mechanical integrity of the assembly is regularly verified and documented.
5. Leakage current meets the appropriate limit when measured with all devices connected according to 10.3.5.2 or 10.3.5.3.
6. Means are employed to assure that additional devices or nonmedical equipment cannot be connected to the multiple outlet extension cord after leakage currents have been verified as safe.

10.2.4 Adapters and Extension Cords.

10.2.4.1 Three-prong to two-prong adapters shall not be permitted.

10.2.4.2 Adapters and extension cords meeting the requirements of 10.2.4.2.1 through 10.2.4.2.3 shall be permitted.

10.2.4.2.1 All adapters shall be listed for the purpose.

10.2.4.2.2 Attachment plugs and fittings shall be listed for the purpose.

10.2.4.2.3 The cabling shall comply with 10.2.3.

10.3 Testing Requirements — Fixed and Portable.

10.3.1 Physical Integrity. The physical integrity of the power cord assembly composed of the power cord, attachment plug, and cord-strain relief shall be confirmed by visual inspection or other applicable tests.

10.3.2 Resistance.

10.3.2.1 For appliances that are used in the patient care vicinity, the resistance between the appliance chassis, or any exposed conductive surface of the appliance, and the ground pin of the attachment plug shall be less than 0.50 ohm under the following conditions:

1. The cord shall be flexed at its connection to the attachment plug or connector.
2. The cord shall be flexed at its connection to the strain relief on the chassis.

10.3.2.2 The requirement of 10.3.2.1 shall not apply to accessible metal parts that achieve separation from main parts by double insulation or metallic screening, or are unlikely to become energized (e.g., escutcheons or nameplates, small screws, and so forth).

10.3.3 Leakage Current Tests.

10.3.3.1 General.

10.3.3.1.1 The requirements in 10.3.3.2 through 10.3.3.5 shall apply to all tests.

10.3.3.1.2 Tests shall be done with the power switch ON and OFF.

10.3.3.2 Resistance Test. The resistance tests of 10.3.3.3 shall be conducted before undertaking any leakage current measurements.
10.3.3.3* Techniques of Measurement. The test shall not be made on the load side of an isolated power system or separable isolation transformer.

10.3.4* Leakage Current Limits. The leakage current limits stated in 10.3.4 and 10.3.5 shall be followed.

10.3.4 Leakage Current — Fixed Equipment.

10.3.4.1 Permanently wired appliances in the patient care vicinity shall be tested prior to installation while the equipment is temporarily insulated from ground.

10.3.4.2 The leakage current flowing through the ground conductor of the power supply connection to ground of permanently wired appliances installed in general or critical care areas shall not exceed 10.0 mA (ac or dc) with all grounds lifted.

10.3.5 Touch Current — Portable Equipment.

10.3.5.1* Touch Current Limits. The touch current for cord-connected equipment shall not exceed 100 A with the ground wire intact (if a ground wire is provided) with normal polarity and shall not exceed 500 A with the ground wire disconnected.

10.3.5.2 If multiple devices are connected together and one power cord supplies power, the leakage current shall be measured as an assembly.

10.3.5.3 When multiple devices are connected together and more than one power cord supplies power, the devices shall be separated into groups according to their power supply cord and the leakage current shall be measured independently for each group as an assembly.

10.3.5.4 Touch Leakage Test Procedure. Measurements shall be made using the circuit, as illustrated in Figure 10.3.5.4, with the appliance ground broken in two modes of appliance operation as follows:

(1) Power plug connected normally with the appliance on
(2) Power plug connected normally with the appliance off (if equipped with an on/off switch)

****INSERT FIGURE HERE****

FIGURE 10.3.5.4 Test Circuit for Measuring Touch Leakage Current.

10.3.5.4.1 If the appliance has fixed redundant grounding (e.g., permanently fastened to the grounding system), the touch leakage current test shall be conducted with the redundant grounding intact.

10.3.5.4.2 Test shall be made with Switch A in Figure 10.3.5.4 closed.

10.3.6* Lead Leakage Current Tests and Limits — Portable Equipment.

10.3.6.1 The leakage current between all patient leads connected together and ground shall be measured with the power plug connected normally and the device on.

10.3.6.2 An acceptable test configuration shall be as illustrated in Figure 10.3.5.4.

10.3.6.3 The leakage current shall not exceed 100 µ A ac or 10 µ A dc for ground wire closed and 500 µ A ac or 50 µ A dc for ground wire open.

10.4 Nonpatient Electrical Appliances and Equipment.

10.4.1 Permanently Connected — Fixed. (Reserved)

10.4.2 Cord- and Plug-Connected — Portable Equipment in Patient Care Room.

10.4.2.1 Nonpatient-care-related electrical equipment, including facility- or patient-owned appliances that are used in the patient care vicinity and will, in normal use, contact patients, shall be visually inspected by the patient’s care staff or other personnel.

10.4.2.2 Any equipment that appears to not be in proper working order or in a worn condition shall be removed from service or reported to the appropriate maintenance staff.

10.4.2.3 Household or office appliances not commonly equipped with grounding conductors in their power cords shall be permitted provided they are not located within the patient care vicinity. Double-insulated appliances shall be permitted in the patient care vicinity.

10.5 Administration.

10.5.1 Responsibilities of Governing Body. (Reserved)

10.5.2 Policies.

10.5.2.1 Testing Intervals.

10.5.2.1.1 The facility shall establish policies and protocols for the type of test and intervals of testing for patient-care-related electrical equipment.

10.5.2.1.2 All patient-care-related electrical equipment used in patient care rooms shall be tested in accordance with 10.3.5.4 or 10.3.6 before being put into service for the first time and after any repair or modification that might have compromised electrical safety.
(1) With the polarity of the power line normal
(2) With the power switch ON and OFF [ROC-524]
(3) With all operating controls in the position to cause maximum leakage current readings

10.3.4 Leakage Current — Fixed Equipment. [ROC-526]

10.3.4.1 Permanently wired appliances in the patient care vicinity shall be tested prior to installation while the equipment is temporarily insulated from ground.

10.3.4.2 The leakage current flowing through the ground conductor of the power supply connection to ground of permanently wired appliances installed in general or critical care areas shall not exceed 10.0 mA (ac or dc) with all grounds lifted.

10.3.5 Touch Current — Portable Equipment. [ROC-527]

10.3.5.1* Chassis Touch Current Limits. The chassis touch current for cord-connected equipment shall not exceed 100 µA with the ground wire intact (if a ground wire is provided) with normal polarity and shall not exceed 500 µA with the ground wire disconnected.

10.3.5.2 If multiple devices are connected together and one power cord supplies power, the leakage current shall be measured as an assembly.

10.3.5.3 When multiple devices are connected together and more than one power cord supplies power, the devices shall be separated into groups according to their power supply cord and the leakage current shall be measured independently for each group as an assembly.

10.3.5.4 Touch Leakage Test Procedure. Measurements shall be made using the circuit, as illustrated in Figure 10.3.5.4, with the appliance ground broken in two modes of appliance operation as follows:

(1) Power plug connected normally with the appliance on
(2) Power plug connected normally with the appliance off (if equipped with an on/off switch)

10.3.5.4.1 If the appliance has fixed redundant grounding (e.g., permanently fastened to the grounding system), the touch leakage current test shall be conducted with the redundant grounding intact.

10.3.5.4.2 Test shall be made with Switch A in Figure 10.3.5.4 closed. [ROC-537]

10.3.5.5 If there is no exposed conductive surface, measurement shall be made with a simulated surface that is also temporarily grounded. [ROC-515]

10.3.6* Lead Leakage Current Tests and Limits, Portable Equipment.

10.3.6.1 The leakage current between all patient leads connected together and ground shall be measured with the power plug connected normally and the device on.

10.3.6.2 An acceptable test configuration shall be as illustrated in Figure 10.3.5.4.

10.3.6.3 The leakage current shall not exceed 100 µA ac or 10 µA dc for ground wire closed and 500 µA ac or 50 µA dc for ground wire open.

10.4 Nonpatient Electrical Appliances and Equipment.

10.4.1 Permanently Connected — Fixed. (Reserved)

10.4.2 Cord- and Plug-Connected — Portable Equipment in Patient Care Room.

10.4.2.1 Nonpatient-care-related electrical equipment, including facility- or patient-owned appliances that are used in the patient care vicinity and will, in normal use, contact patients, shall be visually inspected by the patient's care staff or other personnel. [ROC-528]

10.4.2.2 Any equipment that appears to not be in proper working order or in a worn condition shall be removed from service or reported to the appropriate maintenance staff.

10.4.2.3 Household or office appliances not commonly equipped with grounding conductors in their power cords shall be permitted provided they are not located within the patient care vicinity. Double-insulated appliances shall be permitted in the patient care vicinity.

10.5 Administration.

10.5.1 Responsibilities of Governing Body. (Reserved)

10.5.2 Policies.

10.5.2.1 Testing Intervals.

10.5.2.1.1 The facility shall establish policies and protocols for the type of test and intervals of testing for patient-care-related electrical equipment.

10.5.2.1.2 All patient-care-related electrical equipment used in patient care rooms shall be tested in accordance with 10.3.5.4 or 10.3.6 before being put into service for the first time and after any repair or modification that might have compromised electrical safety. [ROC-529]

10.5.2.2 Protection of Patients with Direct Electrical Pathways to the Heart.

10.5.2.2.1 Only equipment that is specifically designed for the purpose [i.e., provided with suitable isolated patient leads or connections (cardiac floating, also known as CF, according to IEC 60601-1:2005)] shall be connected directly to electrically conductive pathways to a patient's heart. [ROC-530]

10.5.2.2.2 The facility shall have a policy that prohibits the use of external cardiac pacemakers and pacing leads with external terminals that are not properly protected from potentially hazardous contact with conductive surfaces.
10.5.2.2 Protection of Patients with Direct Electrical Pathways to the Heart.

10.5.2.2.1 Only equipment that is specifically designed for the purpose [i.e., provided with suitable isolated patient leads or connections (cardiac floating, also known as CF, according to IEC 60601-1)] shall be connected directly to electrically conductive pathways to a patient’s heart.

10.5.2.3 Adapters and Extension Cords.

10.5.2.3.1 Adapters and extension cords meeting the requirements of 8.4.1.2.5 shall be permitted to be used.

10.5.2.3.2 Three-to-two-prong adapters shall not be permitted.

10.5.2.3.3 The wiring shall be tested for all of the following:

1. Physical integrity
2. Polarity
3. Continuity of grounding at the time of assembly and periodically thereafter

10.5.2.4 Devices Likely To Be Used During Defibrillation. Devices that are critical to patient safety and that are likely to be attached to the patient when a defibrillator is used (such as ECG monitors) shall be rated as “defibrillator proof.”

10.5.2.5 System Demonstration. Any system consisting of several electric appliances shall be demonstrated to comply with this code as a complete system.

10.5.2.6 Electrical Equipment Systems. Purchase contracts for electrical equipment systems, such as nurse call and signaling that consist of interconnected elements, shall require all of the following:

1. That the elements be intended to function together
2. That the manufacturers provide documentation for such interconnection
3. That the systems be installed by personnel qualified to do such installations

10.5.2.7 Appliances Not Provided by the Facility. Policies shall be established for the control of appliances not supplied by the facility.

10.5.3 Servicing and Maintenance of Equipment.

10.5.3.1 The manufacturer of the appliance shall furnish documents containing at least a technical description, instructions for use, and a means of contacting the manufacturer.

10.5.3.1.1 These documents shall include the following where applicable:

1. Illustrations that show the location of controls
2. An explanation of the function of each control
3. Illustrations of proper connection to the patient or other equipment or both
4. Step-by-step procedures for testing and proper use of the appliance
5. Safety considerations in use and servicing of the appliance
6. Precautions to be taken if the appliance is used on a patient simultaneously with other electric appliances
7. Schematics, wiring diagrams, mechanical layouts, parts lists, and other pertinent data for the appliance
8. Instructions for cleaning, disinfection or sterilization
9. Utility supply requirements (electrical, gas, ventilation, heating, cooling, etc.)
10. An explanation of figures, symbols, and abbreviations on the appliance
11. Technical performance specifications
12. Instructions for unpacking, inspection, installation, adjustment, and alignment
13. Preventive and corrective maintenance and repair procedures

10.5.3.1.2 Service manuals, instructions, and procedures provided by the manufacturer shall be considered in the development of a program for maintenance of equipment.

10.5.4 During Administration of Oxygen Therapy.

10.5.4.1 Electrical Equipment in Oxygen-Enriched Atmospheres. Appliances or part(s) of an appliance or system (e.g., pillow speaker, remote control, pulse oximeter probe) to be used in the site of intentional expulsion shall comply with one of the following:

1. Be listed for use in oxygen-enriched atmospheres.
2. Be sealed so as to prevent an oxygen-enriched atmosphere from reaching electrical components. The sealing material shall be of the type that will still seal even after repeated exposure to water, oxygen, mechanical vibration, and heating from the external circuitry.
3. Be ventilated so as to limit the oxygen concentration surrounding electrical components to below 23.5 percent by volume.
4. Have both of the following characteristics:
   a. No hot surfaces over 300°C (573°F), except for small (less than 2 W) hermetically sealed heating elements
such as light bulbs.

(b) No exposed switching or sparking points of electrical energy that fall to the right of the curve for the appropriate type of circuit illustrated in Figure 10.5.4.1(a) through

**FIGURE 10.5.4.1(a) Resistance Circuits (L < 1 mH): Minimum Igniting Currents, Applicable to All Circuits Containing Cadmium, Zinc, or Magnesium.****INSERT FIGURE HERE****

**FIGURE 10.5.4.1(b) Resistance Circuits (L < 1 mH): Minimum Igniting Currents, Applicable to Circuits Where Cadmium, Zinc, or Magnesium Can Be Excluded.****INSERT FIGURE HERE****

**FIGURE 10.5.4.1(c) Inductance Circuits (L > 1 mH): Minimum Igniting Currents at 24 V, Applicable to All Circuits Containing Cadmium, Zinc, or Magnesium.****INSERT FIGURE HERE****

**FIGURE 10.5.4.1(d) Inductance Circuits (L > 1 mH): Minimum Igniting Currents for Various Voltages, Applicable to All Circuits Containing Cadmium, Zinc, or Magnesium.****INSERT FIGURE HERE****

**FIGURE 10.5.4.1(e) Inductance Circuits (L > 1 mH): Minimum Igniting Currents at 24 V, Applicable Only to Circuits Where Cadmium, Zinc, or Magnesium Can Be Excluded.****INSERT FIGURE HERE****

**FIGURE 10.5.4.1(f) Capacitance Circuits Minimum Ignition Voltages. (The curves correspond to values of current-limiting resistance as indicated. The curve marked Sn is applicable only where cadmium, zinc, or magnesium can be excluded.)

10.5.4.2 When only the remote control or signal leads of a device are to be used in the site of intentional expulsion, only the control or signal leads shall be required to comply with 10.5.4.1.

10.5.4.3 Subparagraphs 10.5.4.1 and 10.5.4.2 shall not apply to small (less than 2 W), hermetically sealed heating elements such as light bulbs.

10.5.4.4 Electrical equipment sold with the intent to be used in oxygen-enriched atmospheres shall be listed for use in oxygen-enriched atmospheres.

10.5.4.5* Electrical equipment used within oxygen delivery equipment shall be listed for use in oxygen-enriched atmospheres in accordance with ANSI/AAMI ES60601-1.

10.5.4.6* High-energy-delivering probes (such as defibrillator paddles) or other electrical devices that do not comply with 10.5.4.1 and 10.5.4.2 that are deemed essential to the care of an individual patient and must be used within an administration site or within oxygen-delivery equipment shall be permitted.

10.5.5 Laboratory.

10.5.5.1* The laboratory shall establish policies and protocols for the type of test and intervals of testing for appliances.

10.5.5.2* The physical integrity of the power cord, attachment plug, and cord strain-relief shall be confirmed at least annually by visual inspection and other appropriate tests.

10.5.5.3 Instruction Manuals.

10.5.5.3.1 A permanent file of instruction and maintenance manuals shall be maintained and be accessible.

10.5.5.3.2 The file of manuals shall be in the custody of the engineering group responsible for the maintenance of the appliance.

10.5.5.3.3 Duplicate instruction and maintenance manuals shall be available to the user.

10.5.5.3.4 Any safety labels and condensed operating instructions on an appliance shall be maintained in legible condition.

10.5.5.3.5 Documentation.

10.5.5.3.6 A record shall be maintained of the tests required by this chapter and associated repairs or modifications.

10.5.5.3.7 At a minimum, this record shall contain all of the following:

(1) Date
10.5.3 Subparagraphs 10.5.4.1 and 10.5.4.2 shall not apply to small (less than 2 W), hermetically sealed heating elements such as light bulbs. [ROC-537]

10.5.4.4 Electrical equipment sold with the intent to be used in oxygen-enriched atmospheres shall be listed for use in oxygen-enriched atmospheres.

10.5.4.5* Electrical equipment used within oxygen delivery equipment shall be listed for use in oxygen-enriched atmospheres in accordance with ANSI/AAMI ES60601-1:2005.

10.5.4.6* High-energy-delivering probes (such as defibrillator paddles) or other electrical devices that do not comply with 10.5.4.1 and 10.5.4.2 that are deemed essential to the care of an individual patient and must be used within an administration site or within oxygen-delivery equipment shall be permitted. [ROC-537]

10.5.5 Laboratory.

10.5.5.1* The laboratory shall establish policies and protocols for the type of test and intervals of testing for each appliance.
At a minimum, this record shall contain all of the following:

1. Date
2. Unique identification of the equipment tested
3. Indication of which items have met or have failed to meet the performance requirements of 10.5.6.2 [ROC-537]

10.5.6.3 Test Logs. A log of test results and repairs shall be maintained and kept for a period of time in accordance with a health care facility’s record retention policy.

10.5.7 Use. (Reserved)

10.5.8 Qualification and Training of Personnel.

10.5.8.1* Personnel concerned for the application or maintenance of electric appliances shall be trained on the risks associated with their use.

10.5.8.1.1 The health care facilities shall provide programs of continuing education for its personnel.

10.5.8.1.2 Continuing education programs shall include periodic review of manufacturers’ safety guidelines and usage requirements for electrosurgical units and similar appliances.

10.5.8.2 Personnel involved in the use of energy-delivering devices including, but not limited to, electrosurgical, surgical laser, and fiberoptic devices shall receive periodic training in fire suppression.

Chapter 11 Gas Equipment

11.1 Applicability.

11.1.1* This chapter shall apply to the use, at normal atmospheric pressure, of all of the following:

1. Nonflammable medical gases
2. Vapors and aerosols
3. Equipment required for their administration

11.1.2 When used in this chapter, the term oxygen shall be intended to mean 100 percent oxygen as well as mixtures of oxygen and air.

11.1.3* This chapter shall not apply to special atmospheres, such as those encountered in hyperbaric chambers.

11.2 Cylinder and Container Source. [ROP-360]

11.2.1 Cylinders and containers shall comply with 5.1.3.1.

11.2.2 Cylinder valve outlet connections shall conform to CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1) (includes Pin-Index Safety System for medical gases). [See 5.1.3.1.]

11.2.3 When low-pressure threaded connections are employed, they shall be in accordance with the CGA V-5, Diameter-Index Safety System (Noninterchangeable Low Pressure Connections...
11.2.4 Low-pressure quick-coupler connections shall be non-interchangeable between gas services.

11.2.5 Regulators and gauges intended for use in high-pressure service shall be listed for such service.

11.2.6 Pressure-reducing regulators shall be used on high-pressure cylinders to reduce the pressure to working pressures.

11.2.7 Approved regulators or other gas-flow control devices shall be used to reduce the cylinder pressure of every cylinder used for medical purposes. All such devices shall have connections so designed that they attach only to cylinders of gas for which they are designated.

11.2.8 Equipment that will permit the intermixing of different gases, either through defects in the mechanism or through error in manipulation in any portion of the high-pressure side of any system in which these gases might flow, shall not be used for coupling cylinders containing compressed gases.

11.2.9 Cylinder valve outlet connections for oxygen shall be Connection No. 540 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).

11.2.10 Cylinder valve outlet connections for nitrous oxide shall be Connection No. 326 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).

11.3 Cylinder and Container Storage Requirements.

11.3.1 Storage for nonflammable gases equal to or greater than 85 m³ (3000 ft³) at STP shall comply with 5.1.3.3.2 and 5.1.3.3.3.

11.3.2 Storage for nonflammable gases greater than 8.5 m³ (300 ft³) but less than 85 m³ (3000 ft³) shall comply with the requirements in 11.3.2.1 through 11.3.2.3.

11.3.2.1 Storage locations shall be outdoors in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors (or gates outdoors) that can be secured against unauthorized entry.

11.3.2.2 Oxidizing gases, such as oxygen and nitrous oxide, shall not be stored with any flammable gas, liquid, or vapor.

11.3.2.3 Oxidizing gases such as oxygen and nitrous oxide shall be separated from combustibles or materials by one of the following:

1. A minimum distance of 6.1 m (20 ft)
(2) Unique identification of the equipment tested
(3) Indication of which items have met or have failed to meet the performance requirements of 10.5.6.2
10.5.6.3 Test Logs. A log of test results and repairs shall be maintained and kept for a period of time in accordance
with a health care facility's record retention policy.
10.5.7 Use. (Reserved)
10.5.8 Qualification and Training of Personnel.
10.5.8.1* Personnel concerned for the application or maintenance of electric appliances shall be trained on the risks
associated with their use.
10.5.8.1.1 The health care facilities shall provide programs of continuing education for its personnel.
10.5.8.1.2 Continuing education programs shall include periodic review of manufacturers' safety guidelines and usage
requirements for electrosurgical units and similar appliances.
10.5.8.2 Personnel involved in the use of energy-delivering devices including, but not limited to, electrosurgical,
surgical laser, and fiberoptic devices shall receive periodic training in fire suppression.
10.5.8.3 Equipment shall be serviced by qualified personnel only.

Substantiation: This chapter was revised to correlate with AAMI ES 60601-1:2005.
1. 8.4.1.2.1.2 was modified to correlate with international standards and the use of functional earth connections as
opposed to protective earth connections.
2. 8.4.1.2.4.3 was modified as this requirement was redundant.
3. 8.4.1.3.5.6 was deleted as in practice this is not an issue.
4. 8.4.1.3.3.4 was deleted in another section, therefore it is not needed here.
5. 8.4.1.3.5 Chassis was deleted to correlate with the IEC.
6. New section relating to protection of patients with direct electrical pathways to the heart was added for protection to
the patient.
7. 8.5.2.1.9 was deleted as it's not practical to specify every piece of equipment.
8. 8.5.2.1.11.2 was deleted this is confusing for the vendors.
9. 8.5.2.2 was expanded to include a detailed list of what is applicable for the service and maintenance manuals.

Committee Meeting Action: Accept
Committee Statement: This chapter has been renumbered to Chapter 10 in the preprint.

99-384 Log #199 HEA-MED Final Action: Reject
(8.4.1.3.3 through 8.4.2.2.1.2)

Submitter: John T. Collins, American Society for Healthcare Engineering
Recommendation: Delete sections 8.4.1.3.3 through 8.4.2.2.1.2. Replace the deleted text with the following proposed
text:

The facility shall require that the manufacturers of patient care-related electrical appliances provide testing results
documenting the compliance of that appliance of that application with NFPA 99 - 2005 sections 10.2.13.3 through
10.2.13.5.2.

Substantiation: A review of the FDA database for medical device reporting (MAUDE reports) since 1983 indicates no
reports of patient injury or death from leakage current. Facility testing of new medical devices for leakage testing does
not increase patient safety and is a drain on precious healthcare resources that should be devoted to accomplishing
tasks proven to promote patient care and safety.

Committee Meeting Action: Reject
Committee Statement: The substantiation does not support the recommendation. History shows there is no events in
the field regarding injuries or deaths due to leakage current.
8.5.2.1.2 All appliances used in patient care areas shall be tested in accordance with 8.4.1.3 or 8.4.2.2.1 before being put into service for the first time and after repair or modification. Patient care related electrical appliances shall be retested at intervals determined by their normal location or area of normal use, but not exceeding the intervals listed below:

1. General care areas - 12 months
2. Critical care areas - 6 months
3. Wet locations - 6 months

Exception No. 1: The testing intervals listed are intended to be nominal values, and facilities shall be permitted to adopt a protocol using either longer or shorter intervals provided that there is a documented justification based on previous safety testing records for the equipment in question, unusually light or heavy utilization, or similar considerations.

Exception No. 2: Facility owned household or other appliances that are used in the patient care vicinity, but that are not intended to contact the patient, shall be tested at intervals deemed appropriate by the facility. The facility shall be permitted to structure a testing protocol and frequency for some equipment that might be more limited than that prescribed in 8.4.1.3.

Substantiation: A review of the FDA database for medical device reporting (MAUDE reports) since 1983 does not support the ongoing need for this level of equipment testing to support patient safety. Any unneeded test or procedure is a drain on precious healthcare resources that should be devoted to accomplishing tasks proven to promote patient care and safety.

Committee Meeting Action: Accept in Principle

Revise to read:

8.5.2.1.2 All patient-care-related electrical equipment used in patient care rooms shall be tested in accordance with 8.4.1.3.5.5 or 8.4.1.3.6 before being put into service for the first time and after any repair or modification that might have compromised electrical safety.

Committee Statement: Although the committee accepted the recommendation in principle, they do not feel the submitter’s substantiation goes far enough.

The frequency of testing is up to the facility and is equipment dependent. This action further substantiates 8.5.2.1.2.1. This will be section 10.5.2.1.2 in the preprint.
99-386  Log #410 HEA-MED
(8.5.2.3, 8.5.5, A.11.8.2.3, D.9.2 through D.9.4)

Submitter: Dale Woodin, ASHE-American Society for Healthcare Engineering of the American Hospital Association (AHA)

Recommendation: Revise text as follows:
Incorporate NFPA 115 by reference into NFPA 99 by doing the following:
1. Add references to NFPA 115 in the following paragraphs of NFPA 99.
   a. Paragraph "8.5.2.3. During Surgery"
   b. Paragraph "8.5.5. Qualification and Training of Personnel"
   c. Paragraph "A.11.8.2.3. Examples of severe and unusual hazards....."
2. Update paragraph D.9.2. to reference current ANSI publications in paragraph 2.3.1.of NFPA 115.
3. Update paragraph D.9.3. to reference current IEC publications in paragraph 2.3.3. of NFPA 115.
4. Update D.9.4. to reference current US government publications in paragraph 2.3.4. of NFPA 115.

Substantiation: The current 2003 edition of NFPA 115 was only recently approved as an American National Standard in July of 2003. In the current edition, the document was changed from a recommended practice to a standard. At that point, all of the language within the body of the document contained enforceable language and any recommendations or advisory information has been moved to the annexes.
This is not original material; its reference/source is as follows:
Proposing revision on behalf of the ASHE Environmental Safety Workgroup.
Committee Meeting Action: Reject
Committee Statement: No language was provided for inclusion in the document.

99-387  Log #43 HEA-MED
(Chapter 9)

Submitter: Burton R. Klein, Burton Klein Associates

2. Create a new Chapter 10, titled "Gas Equipment Requirements for Existing Facilities."
3. Insert Sections 9.6, 9.7, and 9.9 into new Chapter 10, renumbered as Sections 10.1, 10.2, and 10.3 respectively.
4. Revise title of Chapter 9 to "Gas Equipment Requirements for New Facilities."
5. Renumber current Chapters 10 to 21 as 11 to 22, respectively.

Substantiation: Make it easier for users and enforcers of document to see which requirements are applicable to new facilities, and which are applicable to existing facilities. (In the similar fashion to arrangement in NFPA 101.)
Committee Meeting Action: Reject
Committee Statement: The intent is to not have any differences between new and used equipment.

99-388  Log #104 HEA-MED
(Chapter 9)

Submitter: Corky Bishop, Medical Gas Management, Inc.

Recommendation: Include all of Chapter 9 in NFPA 99C.

Substantiation: Chapter 9 currently is not printed in NFPA 99C. Many sections from the gas and vacuum systems chapter have been relocated to Chapter 9, gas equipment. These requirements for inspection, maintenance, training, and record keeping should be included in NFPA 99C.
Committee Meeting Action: Reject
Committee Statement: This is not under the jurisdiction of this committee. Also NFPA 99C is an extracted document from NFPA 99.
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<tr>
<th>Log #</th>
<th>HEA-MED</th>
<th>Final Action: Accept</th>
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<tbody>
<tr>
<td>99-390</td>
<td>Log CP902</td>
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<td>(9.1.2)</td>
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<tr>
<td><strong>Submitter:</strong> Technical Committee on Medical Equipment, <strong>Recommendation:</strong> Revise to read as follows: 9.1.2 When used in this chapter, the term oxygen shall be intended to mean oxygen as well as mixtures of oxygen and air. <strong>Substantiation:</strong> There is no 100 percent oxygen. This will be 11.1.2 in the ROP preprint. <strong>Committee Meeting Action:</strong> Accept</td>
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<td>99-391</td>
<td>Log CP509</td>
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<td>(9.3.1)</td>
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<td><strong>Submitter:</strong> Technical Committee on Medical Equipment, <strong>Recommendation:</strong> Delete Section 9.3.1. <strong>Substantiation:</strong> Not a requirement. Superfluous language. <strong>Committee Meeting Action:</strong> Accept</td>
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<td>99-392</td>
<td>Log CP535</td>
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<td>(9.3.3, 9.3.4)</td>
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<td><strong>Submitter:</strong> Technical Committee on Medical Equipment, <strong>Recommendation:</strong> In 9.3.3 and 9.3.4 change the reference to: (5.1.3.1.4) <strong>Substantiation:</strong> Corrected an error in the reference. <strong>Committee Meeting Action:</strong> Accept</td>
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<td>99-393</td>
<td>Log CP904</td>
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<td>(9.3.6, 9.3.7, 9.3.8)</td>
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<td><strong>Submitter:</strong> Technical Committee on Medical Equipment, <strong>Recommendation:</strong> Change the term &quot;regulator&quot; to &quot;pressure reducing regulators&quot; in 9.3.6 and 9.3.8. In 9.3.7 revise to read as follows: &quot;Pressure-reducing regulators shall be used on high-pressure cylinders to reduce the cylinder pressure to working pressures&quot;. <strong>Substantiation:</strong> The terms were changed to be consistent. This will be sections 11.2.5, 11.2.6 and 11.2.7. <strong>Committee Meeting Action:</strong> Accept</td>
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<td>99-394</td>
<td>Log CP909</td>
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<td>(9.3.6, 9.6.3.3.4, 9.7.2.1(1)(2), 9.7.2.4(1)(4), 9.7.2.6)</td>
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<td><strong>Submitter:</strong> Technical Committee on Medical Equipment, <strong>Recommendation:</strong> Change the term &quot;regulator&quot; to &quot;pressure-reducing regulator&quot; <strong>Substantiation:</strong> Changed the terms for consistency with definition. These will be sections 11.2.5, 11.5.3.3.4, 11.6.2.1(1)(2), 11.6.2.4(1)(4). <strong>Committee Meeting Action:</strong> Accept</td>
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99-395  Log #CP536  HEA-MED
(9.3.9)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation:  Change 9.3.9 to read: "9.3.9*  Equipment that will permit the intermixing of different gases, either through defects in the mechanism or through error in manipulation in any portion of the high-pressure side of any system in which these gases might flow, shall not be used for coupling joining cylinders containing compressed gases."
Substantiation:  Joining is the correct terminology.
Committee Meeting Action: Accept

99-396  Log #CP903  HEA-MED
(9.3.10, 9.3.11)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation:  Revise to read as follows:
9.3.10 Cylinder valve outlet connections for oxygen shall be Connection No. 540 or 870 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).
9.3.11 Cylinder valve outlet connections for nitrous oxide shall be Connection No. 326 or 910 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).
Substantiation:  The pin index number is being added as they are used in health care facilities. These sections will be 11.2.9 and 11.2.10 in the ROP preprint.
Committee Meeting Action: Accept

99-397  Log #CP537  HEA-MED
(9.3.10, 9.3.11)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation:  Revise to read as follows:
"11.2.9 Cylinder valve outlet connections for oxygen shall be Connection No. 540 or Connection No. 870 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).
11.2.10 Cylinder valve outlet connections for nitrous oxide shall be Connection No. 326 or Connection No. 910 as described in CGA V-1, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1).
11.3 Cylinder and Container Storage Requirements."
Substantiation:  Corrected the connection type.
Committee Meeting Action: Accept
Joshua W. Elvove, Aurora, CO

Recommendation: Revise 9.4.1 as follows:

Storage for nonflammable gases greater than 85 m$^3$ (3000 ft$^3$) compressed shall comply with 5.1.3.3.2 and 5.1.3.3.3 the requirements of 9.4.1.1 through 9.4.1.x. Extract only those specific requirements from 5.1.3.3.2 and 5.1.3.3.3 that are necessary for the safe storage of this quantity of nonflammable gases.

Substantiation: 5.1.3.3 applies to manifolded systems, not storage of nonflammable gases. The title of 5.1.3.3.3.1 specifically says “Ventilation of Locations for Manifolds.” As such, the requirements of this section are potentially conflicting (not applicable?), if not excessive. The storage requirements for nonflammable gases of this quantity may warrant additional safeguards than those specified by 9.4.2, but those safeguards should be specifically written into 9.4.1, rather than referencing all the requirements for manifolded systems as specified 5.1.3.3.2 and 5.1.3.3.3. I have not proposed which items from 5.1.3.3.2 and 5.1.3.3.3 that should be placed into 9.4.1.1 through 9.4.1.1x, and leave this to the committee experts. However, I do suggest that 9.4.1 only contain those requirements that pertain to storage of nonflammable gases (oxygen?) and not those that pertain to manifolded systems (i.e., why worry about accumulation of off-gasing which might be expected for manifolded systems, but not ordinary container storage?).

Though I have nothing to propose, I also suggest some clarifying text be placed into an annex note that lists examples of nonflammable gases applicable to section 9.4. Oxygen is the main concern and principle material typically found in health care facilities requiring such attention. It would be good for the annex note to list other gases of concern. Conversely, it would be good for the annex note to also list those gases that should not be covered by this section because they may be less of a concern (e.g., carbon dioxide, nitrogen) as we really don’t want to start limiting the amount of carbon dioxide fire extinguishers or carbon dioxide containers used for pressuring soda in the cafeteria to less than 300 cu ft per smoke compartment.

Committee Meeting Action: Reject
Committee Statement: This topic is being addressed by the HEA-MEC committee.

Technical Committee on Medical Equipment,

Recommendation: In sections 9.4.1, 9.4.2, 9.4.3, delete the word "compressed".
Also move Table C.13.5 to Annex A as A.9.4.1, A.9.4.2 and A.9.4.3.

Substantiation: The section pertains to both liquid and compressed gases.
Committee Meeting Action: Accept

Corky Bishop P.E., Medical Gas Management, LLC

Recommendation: Revise text to read as follows:

9.4.1 Storage for nonflammable gases equal to or greater than 85 m$^3$ (3000 ft$^3$) at STP $\text{compressed}$ shall comply with 5.1.3.3.2 and 5.1.3.3.3.
9.4.2 Storage for nonflammable gases greater than 8.5 m$^3$ (300 ft$^3$) but less than 85 m$^3$ (3000 ft$^3$) at STP $\text{compressed}$ shall comply with the requirements in 9.4.2.1 through 9.4.2.3.

Substantiation: This should refer to gas at standard temperature and pressure. This will be consistent with 5.1.3.3.3.1(D) and 14.3.5.1(3)(c).
Committee Meeting Action: Accept
99-401    Log CP538 HEA-MED
(9.4.2.4)                              Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise 9.4.2.4 to read as follows: "Cryogenic liquid container storage shall comply with 5.1.3.5.12."
Substantiation: The term cryogenic liquid is industry standard terminology.
Committee Meeting Action: Accept

99-402    Log CP906 HEA-MED
(9.4.2.5, 9.4.2.7, 9.4.2.8, 9.4.2.10)                         Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Change "shall meet" to "shall comply with".
Substantiation: changed for consistency. These section are 11.3.2.5, 11.3.2.6, 11.3.2.7, 11.3.2.9 in the ROP preprint.
Committee Meeting Action: Accept

99-403    Log #205 HEA-MED
(9.4.2.6)                              Final Action: Accept

Submitter: Dale Woodin, American Society for Healthcare Engineering
Recommendation: Revise text to read as follows:
9.4.2.6 When small-size (A, B, D, or E) cylinders are in use, they shall be attached to a cylinder stand or to a therapy apparatus of sufficient size to render the entire assembly stable. medical equipment designed to receive and hold compressed gas cylinders.
Substantiation: The use of 'medical equipment' would more accurately reflect other items designed to hold cylinders such as anesthesia machines, wheelchairs, and stretchers.
This is not original material; its reference/source is as follows:
I am proposing this revision on behalf of Jeffrey Krebs of Christiana Care Health Services
Committee Meeting Action: Accept
Committee Statement: The correct reference is 9.4.3.3.

99-404    Log CP510 HEA-MED
(9.4.2.6)                              Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Delete Section 9.4.2.6.
Substantiation: This requirement is applicable to central supply locations, manifold rooms, which are covered in Chapter 5.
Committee Meeting Action: Accept

99-405    Log CP910 HEA-MED
(9.4.2.8)                              Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Change "restraint" to "restraints"
Substantiation: Editorial. This will be 11.3.2.7 in the ROP preprint.
Committee Meeting Action: Accept
99-406  Log #CP511 HEA-MED
(9.4.2.10)

**Final Action:** Accept

**Submitter:** Technical Committee on Medical Equipment,

**Recommendation:** Change the reference in Section 9.4.2.10 to 5.3.13.1.2(4).

**Substantiation:** The reference was corrected.

**Committee Meeting Action:** Accept

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99-407  Log #CP539 HEA-MED
(9.4.2.11)

**Final Action:** Accept

**Submitter:** Technical Committee on Medical Equipment,

**Recommendation:** Revise 9.4.2.11 to read as follows: "Gas cylinder and cryogenic liquid container storage shall comply with 5.1.3.5.12"

**Substantiation:** The term cryogenic liquid is industry standard terminology.

**Committee Meeting Action:** Accept

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99-408  Log #405 HEA-MED
(9.4.5)

**Final Action:** Accept in Principle

**Submitter:** Joshua W. Elvove, Aurora, CO

**Recommendation:** Add new 9.4.5 as follows:

9.4.5 Empty cylinders shall be segregated from full cylinders.

**Substantiation:** For patient safety, to ensure empty cylinders aren’t mistaken for full cylinders and to reduce the risk of infection, since empty cylinders would have been in contact with patients.

**Committee Meeting Action:** Accept in Principle

Revise to read as follows:

9.4.5 If empty and full cylinders are stored within the same enclosure, empty cylinders shall be segregated from full cylinders.

9.4.5.1 When the facility employs cylinders with integral pressure gauges, it shall establish the threshold pressure at which a cylinder is considered empty.

**Committee Statement:** The facility can determine when the cylinder is considered empty by using it's own criteria. This will be in section 11.6.5.2 and 11.6.5.2.1 in the preprint.

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99-409  Log #CP911 HEA-MED
(9.5.1.2)

**Final Action:** Accept

**Submitter:** Technical Committee on Medical Equipment,

**Recommendation:** Revise to read: "...attachment of a small cylinder equipped with a flush-type valve..."

**Substantiation:** Editorial. This will be 11.4.1.2 of the ROP preprint.

**Committee Meeting Action:** Accept
99-410  Log #CP912  HEA-MED
(9.5.1.3.1(1))  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Change to read: "Alteration of a pipeline hose or fittings"
Substantiation: Editorial. This will be 11.4.1.3.1(1) in the ROP preprint.
Committee Meeting Action: Accept

99-411  Log #CP913  HEA-MED
(9.5.1.4)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Change to read: "...shall be of the Connection No. 860 type..."
Substantiation: Correct to be consistent with V-1. This will be 11.4.1.4 of the ROP preprint.
Committee Meeting Action: Accept

99-412  Log #CP540  HEA-MED
(9.5.1.4)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise 9.5.1.4 to read: "Yoke-type connections between anesthesia apparatus and flush-type cylinder valves (commonly used with anesthetic gas cylinders) shall be of Connection No. 860 type in accordance with CGA V-1, Compressed Gas Cylinder Valve Outlet and Inlet Connections (ANSI B57.1)."
Substantiation: The term cryogenic liquid is industry standard terminology.
Committee Meeting Action: Accept

99-413  Log #CP914  HEA-MED
(9.5.2.4)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Change to read: "...made of transparent or translucent material..."
Substantiation: Allows a wider variety of materials. This will be section 11.4.2.4 of the ROP preprint.
Committee Meeting Action: Accept

99-414  Log #CP541  HEA-MED
(9.6.1.2.1)  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise to read as follows: "9.6.1.2.1 Flammable or combustible aerosols or vapors, such as alcohol, shall not be used in oxygen-enriched atmospheres."
Substantiation: Editorial.
Committee Meeting Action: Accept
Areas designated for the servicing of oxygen equipment shall be clean, free of oil and grease, and not used for the repair of other equipment. Only nonsparking tools shall be used in this area.

Gas and Vacuum System hazards are documented in NFPA 99, Annex B Nature of Hazards:
- In an oxygen-enriched atmosphere, materials that are flammable and combustible in air ignite more easily and burn more vigorously.
- The occurrence of a fire requires the presence of combustible or flammable materials, an atmosphere of oxygen or other oxidizing agents, and a source of ignition. Combustible materials can be unavoidably present when oxygen is being administered, but...ignition sources are avoidable.
- Oxygen-enriched atmospheres can exist in the immediate vicinity of all oxygen administration equipment.

NFPA 99, section 9.4.2.9 requires that smoking, open flames, electric heating elements, and other sources of ignition shall be prohibited within storage locations and within 6.1m (20 ft) of outside storage locations.

NFPA 99, section 9.6.1.1 specifies that sources of ignition should be eliminated in administration of gas equipment. An oxygen-enriched atmosphere documents a flammability hazard.

NFPA 30, Flammable and Combustible Liquids, Chapter 6, section 6.5.1 lists frictional heat or sparks as sources of ignition of flammable vapors and precaution shall be taken to control ignition sources.

Recognizing the potential for steel tools to be an ignition source in flammable environments, the Occupational Safety & Health Administration (OSHA) provides guidance in booklet 3080 Hand and Power Tools, 2002 revised, “iron and steel hand tools may produce sparks that can be an ignition source around flammable substances. Where this hazard exists, spark-resistant tools should be used.”

NFPA 99, Annex B Nature of Hazards also cautions that improper maintenance, handling, or assembly of equipment can result in personal injury, property damage, or fire.

NFPA 99 can better mitigate the flammability hazards by specifying the use of nonsparking tools. Without this specification, steel tools are likely to be used which can be an ignition source. The risk of ignition introduced by steel tools can be avoided through the specific reference for the use of nonsparking tools.

This is not original material; its reference/source is as follows:

Committee Meeting Action: Reject
Committee Statement: There is no reason to use non-sparking tools for oxygen. These tools are typically used with hydrogen.
Technical Committee on Medical Equipment,

Recommendation: Revise to read as follows:

9.6.2.2 Transfilling Cylinders.
9.6.2.2.1 Mixing of compressed gases in cylinders shall be prohibited.
9.6.2.2.2 Transfilling of gaseous oxygen from one cylinder to another shall be in accordance with CGA P-2.5, Transfilling of High Pressure Gaseous Oxygen to be Used for Respiration.
9.6.2.2.3 Transfilling of any gases from one cylinder to another in patient care rooms of health care facilities shall be prohibited.

9.6.2.3 Transfilling Liquid Oxygen. Transfilling of liquid oxygen shall comply with 9.6.2.3.1 or 9.6.2.3.2, as applicable.
9.6.2.3.1 Transfilling to liquid oxygen base reservoir containers or to liquid oxygen portable containers over 344.74 kPa (50 psi) shall include the following:

(1) A designated area separated from any portion of a facility wherein patients are housed, examined, or treated by a fire barrier of 1 hour fire-resistive construction.

(2) The area is mechanically ventilated, is sprinklered, and has ceramic or concrete flooring.

(3) The area is posted with signs indicating that transfilling is occurring, and that smoking in the immediate area is not allowed.

(4) The individual transfilling the container(s) has been properly trained in the transfilling procedures.

9.6.2.3.2 Transfilling to liquid oxygen portable containers at 344.74 kPa (50 psi) and under shall include the following:

(1) The area is well-ventilated and has noncombustible flooring.

(2) The area is posted with signs indicating that smoking in the area is not allowed.

(3) The individual transfilling the liquid oxygen portable container has been properly trained in the transfilling procedure.


Substantiation: Standardized on the term Transfilling as it is the industry term.

Committee Meeting Action: Accept
Transfer of gaseous oxygen from one high-pressure cylinder with a volume greater than 15.9 cu. ft. (450L) or at a flow rate greater than 20L/min to another any other cylinder shall be in accordance with CGA P-2.5, Transfilling of High Pressure Gaseous Oxygen to be Used for Respiration.

Subsection 9.6.2.2.2 on transfilling requirements has not been updated to reflect technological advancements in the filling of individual cylinders for ambulatory patient use. Common practice in homes, assisted living facilities, nursing facilities, etc., allow for point of use oxygen generation by oxygen concentrators. These prescription devices separate and concentrate oxygen gas from room air and deliver it to a single patient for supplemental oxygen gas. Recent product developments in the technology of filling single patient cylinders for ambulatory use allow specialized oxygen concentrators and their associated equipment to fill dedicated cylinders under safe and energy limited conditions. These single-user oxygen concentrator systems that fill cylinders at low flow rates with USP oxygen are reviewed and cleared by the FDA under the portable oxygen generator device classification.

Transfilling is listed by the FDA as a drug manufacturing process under the Compressed Medical Gases Guideline (21 CFR 10.90). Transfilling is a regulated process that must meet FDA guidelines for compliance to sections of the current good manufacturing practice (CGMP) regulations for drug products (21 CFR parts 210 and 211). The safety and effectiveness of the transfilling from cylinder to cylinder with medical oxygen gas is regulated under this guidance.

Oxygen concentrators are listed by the FDA as portable oxygen generators and therapeutic devices under Subpart F of 21 CFR Section 868.5440. The safety and effectiveness of the specialized oxygen concentrators and associated equipment have been reviewed and cleared for marketing by the FDA for patient supplemental oxygen users and for filling cylinders for personal ambulatory use. There are no requirements of oxygen concentrators to be regulated by the drug manufacturing sections of the FDA regulations for transfilling. FDA transfilling requirements do not apply to oxygen concentrators and their ambulatory cylinder filling systems.

Adding cylinder size, pressure rating, and flow rate limits to the transfilling requirements will enable clear determination of systems that are not required to meet the transfilling conditions called out in CGA P-2.5.

Limiting the patient use of cylinders to D size or smaller restricts the weight and handling requirements for patient safety and use. Transfilling operations do not typically use cylinders of the D size or smaller. The volumes of D or smaller sized cylinders do not allow for any efficient filling of any other cylinders. The piping system of transfilling equipment is not set up to utilize the smaller cylinder fittings and hardware as a source gas.

Limiting the cylinder or source guidelines to a high pressure (>200 PSIG) setup continues to restrict transfilling to the requirements of CGA P-2.5 as well as continuing to prevent any filling of one cylinder from another in patient care areas. Equipment and volume limits of D size cylinders or smaller are not effective sources of gases that can be transferred to another cylinder and provide the patient with satisfactory volumes of gas for ambulatory use. Oxygen concentrator based filling systems typically use a source gas less than 30 PSIG for safety.

Placing an allowable limit on the flow rate of filling cylinders to low values dramatically reduces any adiabatic heating, frictional heating, heat of compression and other safety issues associated with oxygen gas filling cylinders. The low filling flow rates of the oxygen concentrator based filling systems are controlled by internal hardware components that cannot be changed or overridden by any patient or user.

Oxygen concentrator based filling systems also typically require a proprietary fitting between the filling station and the cylinder. The dedicated mating connector on the patient’s ambulatory cylinder allows only connection to and filling by the specific oxygen concentrator based filling system. A proprietary connector system also prevents any other non-system compatible gas cylinder from being connected to the proprietary system and being inadvertently filled.

Institutional or commercial applications that transfill multiple cylinders at high flow rates (>20L/min.) and with a high pressure (>200 PSIG) cylinder or source for multiple patient use must continue to comply with the conditions and requirements of CGA P-2.5 for use in health care facilities.

Note: Supporting material is available for review at NFPA Headquarters.
Transfer of any gases from one high-pressure cylinder with a volume greater than 15.9 cu. ft (450L) or at a flow rate greater than 20L/min to another any other cylinder in patient care areas of health care facilities shall be prohibited.

Subsection 9.6.2.2.3 on the prohibition of filling cylinders in patient care areas of health care facilities has not been updated to reflect the technology advancements in the filling of individual oxygen cylinders for ambulatory patient use. Current common practice in homes, assisted living facilities, nursing facilities, etc., allow for point of use oxygen generation by oxygen concentrators. These devices separate and concentrate oxygen gas from room air and deliver it to a single patient for supplemental oxygen. Recent developments in the technology of filling patient cylinders for ambulatory use allow oxygen concentrators and their associated equipment to fill cylinders under safe and energy limited conditions. These ambulatory patient use filling systems fill cylinders at low flow rates with USP oxygen as reviewed and cleared by the FDA under device classification 21 CFR Subpart F Section 868.5440 for portable oxygen generators.

Clarification is needed to distinguish between defined transfilling as from one cylinder to another versus the oxygen concentrator based cylinder filling systems. Misinterpretation of transfilling versus concentrator based cylinder filling systems could deny these effective and safe advanced technologies to respiratory patients in health care facilities.

The multiple safeguards and safety features of the ambulatory patient use cylinder filling systems based on oxygen concentrators offer less handling of multiple cylinders, economical filling, reduction in equipment costs, and handling times for the patients, oxygen providers and institutions with increased safety for the patients and facilities.

Adding cylinder size, pressure rating, and flow rate limits to the transfilling requirements will enable clear determination of systems that are allowed and not allowed in the patient care areas of health care facilities.

Limiting the patient use of cylinders to D size or smaller restricts the weight and handling requirements for patient safety and use. Transfilling operations do not typically use cylinders of the D size or smaller. The small volumes of D and smaller sized cylinders do not allow for any efficient transfilling of any other cylinders. Transfilling equipment is not set up to utilize the smaller cylinder fittings and hardware as a source gas.

Limiting the cylinder guidelines to a high pressure (>200 PSIG) setup continues to prevent transferring of gas from a working pressure (<200 PSIG) cylinder to another in patient care areas. Equipment and volume limits of D size cylinders or smaller are not effective sources of gases that can be transfilled to another cylinder and provide the patient with satisfactory volumes of oxygen for ambulatory use. Oxygen concentrator based filling systems typically use a source gas less than 30 PSIG for safety.

Placing an allowable limit on the flow rate of filling cylinders to low values dramatically reduces any adiabatic heating, frictional heating, heat of compression and other safety issues associated with oxygen gas filling cylinders. The low filling flow rates of the oxygen concentrator based filling systems are controlled by hardware components that cannot be changed or overridden by any patient or other user.

Oxygen concentrator based filling system also typically require a proprietary fitting between the filling station and the cylinder. The dedicated mating connector on the patient's ambulatory cylinder allows only connection to and filling by the specific oxygen concentrator based filling system. A proprietary connector system also prevents any other non-system compatible gas cylinder from being connected to the proprietary system and being inadvertently filled.

Institutional or commercial applications that transfill multiple cylinders with high pressure sources and at high flow rates for multiple patient use must continue to comply with the conditions and requirements of CGA P-25 for use in health care facilities. Transfer of any gas from a high pressure (>200 PSIG) cylinder, as in normal transfilling applications, or at high flow rates (>20 L/min.) will continue to be banned from patient care areas.

Note: Supporting material is available for review at NFPA Headquarters.

Committee Meeting Action: Reject

Committee Statement: The proposed wording will create a more restrictive requirement. Mandating a flow rate of 20L/M is difficult to control.
99-420  Log #CP543  HEA-MED  
(9.6.3.3.3, 9.6.3.3.4)  
Final Action: Accept

Submitter: Technical Committee on Medical Equipment,  
Recommendation: Revise to read as follows:

"9.6.3.3.3 Care shall be taken in attaching connections from gas services to equipment and from equipment to patients.

9.6.3.3.4 Fixed or adjustable orifice mechanisms, metering valves, pressure-reducing regulators, and gauges shall not be connected directly to high-pressure cylinders unless specifically listed for such use and provided with appropriate safety devices.

Substantiation: Editorial changes. These will be section 11.5.3.3.3 and 11.5.3.3.4 of the ROP preprint.  
Committee Meeting Action: Accept

99-421  Log #202  HEA-MED  
(9.7.1.1)  
Final Action: Accept in Principle

Submitter: Dale Woodin, American Society for Healthcare Engineering  
Recommendation: Delete text as follows:

9.7.1.1 Purchase specifications shall include the following:

(1) Specification for cylinders
(2) Marking of cylinders, regulators, and valves
(3) Proper connection of cylinders supplied to the facility

(4) Cylinders equipped with valves that include a means to slow the initial opening pressurization shall be permitted.

Substantiation: Remove item 4 under 9.7.1.1, this statement can cause confusion. If something is not prohibited it is already allowed.

This is not original material; its reference/source is as follows:
I am proposing this revision on behalf of the ASHE Gas Equipment Workgroup  
Committee Meeting Action: Accept in Principle

Revise to read:

9.7.1.1 Purchase specifications shall include the following:

(1) Specifications for cylinders  
(2) Marking of cylinders, regulators, and valves  
(3) Proper connections on the cylinders supplied to the facility

Committee Statement: Editorial revision. This will be section 11.6.1.1 in the preprint.

99-422  Log #CP907  HEA-MED  
(9.7.1.1)  
Final Action: Accept

Submitter: Technical Committee on Medical Equipment,  
Recommendation: Revise to read as follows:

8.7.1.1 Purchase specifications shall include the following:

(3) Proper cylinder valve connectors

Substantiation: Clarified the intention of the section. This will be section 11.6.1.1 of the ROP preprint.  
Committee Meeting Action: Accept
99-423  Log #100  HEA-MED
(9.7.1.2)  Final Action: Accept in Principle

Submitter: Corky Bishop P.E., Medical Gas Management, LLC

Recommendation: Delete paragraph 3.

Relocate paragraph 5 to 9.9.1.2.

(3) Proper uses of the medical–surgical vacuum system in order to eliminate practices that reduce the system’s effectiveness, such as leaving suction tips and catheters open when not actually aspirating, and using equipment arrangements that are improperly trapped or are untrapped

(5) Annual training by the supplier on the operation of a bulk cryogenic system when provided.

Substantiation: This section concerns operation and management of cylinders. Paragraph 3 is already included in section 9.9.1 for policies and procedures, administration. The paragraph about training for bulk oxygen systems would fit better there as well.

Committee Meeting Action: Accept in Principle

Delete section 9.7.1.2(3)

Delete section 9.7.1.2(5)

Add new section to read as follows: 9.6.2.1.5 If a bulk cryogenic system is present, the supplier shall provide annual training on its operation.

Committee Statement: Subsection (5) better belongs in section 9.6.2.1.5 and clarifies the requirement.

99-424  Log #CP544  HEA-MED
(9.7.2.2(1))  Final Action: Accept

Submitter: Technical Committee on Medical Equipment,

Recommendation: Revise to read:

“9.7.2.2 Equipment associated with oxygen shall be protected from contamination, which shall include the following specific precautions:

(1) Particles of dust and dirt shall be cleared from cylinder valve openings by slightly opening and closing the valve before applying any fitting to the cylinder valve."

Substantiation: Editorial. This will be section 11.6.2.2 of the ROP preprint.

Committee Meeting Action: Accept
9.7.2.3  Cylinders shall be protected from damage, which shall include the following specific procedures:

1. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.
2. Oxygen cylinders shall not be stored near elevators, gangways, or in locations where heavy moving objects will strike them or fall on them.
3. Cylinders shall be protected from tampering by unauthorized individuals.
4. Cylinders or cylinder valves shall not be repaired, painted, or altered.
5. Safety relief devices in valves or cylinders shall never be tampered with.
6. Valve outlets clogged with ice shall be thawed with warm— not boiling — water.
7. A torch flame shall never be permitted under any circumstances to come in contact with a cylinder, cylinder valve or safety device.
8. Sparks and flame shall be kept away from cylinders.
9. Even if they are considered to be empty, cylinders shall never be used as rollers, supports, or for any purpose other than that for which the supplier intended them.
10. Large cylinders (exceeding size E) and containers larger than 45 kg (100 lb) weight shall be transported on a proper hand truck or cart complying with 11.4.3.1.
11. Freestanding cylinders shall be properly chained or supported in a proper cylinder stand or cart.
12. Cylinders shall not be supported by radiators, steam pipes, or heat ducts.

9.7.2.4  Cylinders and their contents shall be handled with care, which shall include the following specific procedures:

1. Oxygen fittings, valves, pressure-reducing regulators, or gauges shall never be used for any service other than that of oxygen.
2. Gases of any type shall never be mixed in an oxygen cylinder or any other cylinder.
3. Oxygen shall always be dispensed from a cylinder through a pressure-reducing regulator.
4. The cylinder valve shall be opened slowly, with the face of the indicator on the pressure-reducing regulator pointed away from all persons.
5. Oxygen shall be referred to by its proper name, oxygen, not air, and liquid oxygen referred to by its proper name, not liquid air.
6. Oxygen shall never be used as a substitute for compressed air.
7. The markings stamped on cylinders shall not be tampered with because it is against federal statutes to change these markings.
8. Markings used for the identification of contents of cylinders shall not be defaced or removed, including decals, tags, and stenciled marks, except those labels/tags used for indicating cylinder status (e.g. full, in use, empty).
9. The owner of the cylinder shall be notified if any condition has occurred that might permit any foreign substance to enter a cylinder or valve, giving details and cylinder number.
10. Neither cylinders nor containers shall be placed in proximity of radiators, steam pipes, heat ducts, or other sources of heat.
11. Very cold cylinders or containers shall be handled with care to avoid injury.
99-426     Log #CP546  HEA-MED
(9.7.2.6)    Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise to read:
9.7.2.6 Pressure-reducing regulators that are in need of repair or cylinders having valves that do not operate properly shall never be used.

Substantiation: Editorial.
Committee Meeting Action: Accept

99-427     Log #203  HEA-MED
(9.7.3.1)    Final Action: Accept

Submitter: Dale Woodin, American Society for Healthcare Engineering
Recommendation: Delete text as follows:
9.7.3.1 Wrenches and tools used to connect respiratory therapy equipment shall not be required to be nonsparking.
Substantiation: Section 9.7.3.1 can be deleted since there is no requirement to use a non-sparking tool.
This is not original material; its reference/source is as follows:
I am proposing this revision on behalf of the ASHE Gas Equipment Workgroup
Committee Meeting Action: Accept
9.7.3.1 Wrenches and tools used to connect respiratory therapy equipment shall not be required to be nonsparking.

Substantiation:
- Gas and Vacuum System hazards are documented in NFPA 99, Annex B Nature of Hazards:
  - In an oxygen-enriched atmosphere, materials that are flammable and combustible in air ignite more easily and burn more vigorously.
  - Oxygen-enriched atmospheres can exist in the immediate vicinity of all oxygen administration equipment
  - The occurrence of a fire requires the presence of combustible or flammable materials, an atmosphere of oxygen or other oxidizing agents, and a source of ignition. Combustible materials can be unavoidably present when oxygen is being administered, but …ignition sources are avoidable.
- NFPA 99, section 9.7.2.3 (8) requires that sparks and flame to be kept away from cylinders.
- NFPA 99, section 9.6.1.1 specifies that sources of ignition should be eliminated in administration of oxygen gas equipment. An oxygen-enriched atmosphere documents a flammability hazard.
- NFPA 30, Flammable and Combustible Liquids, Chapter 6, section 6.5.1 lists frictional heat or sparks as sources of ignition of flammable vapors and precaution shall be taken to control ignition sources.
- Recognizing the potential for steel tools to be an ignition source in flammable environment, the Occupational Safety & Health Administration (OSHA) provides guidance in booklet 3080 Hand and Power Tools, 2002 revised, “iron and steel hand tools may produce sparks that can be an ignition source around flammable substances. Where this hazard exists, spark-resistant tools should be used.”
- NFPA 99, Annex B Nature of Hazards cautions that improper maintenance, handling, or assembly of equipment can result in personal injury, property damage, or fire.

NFPA 99 can better mitigate the flammability hazards by specifying the use of nonsparking tools. Without this specification, steel tools are likely to be used which can be an ignition source. The risk of ignition introduced by steel tools can be avoided through the specific reference for the use of nonsparking tools.

This is not original material; its reference/source is as follows:
Committee Meeting Action: Reject
Committee Statement: There is no reason to use non-sparking tools for oxygen. These tools are typically used with hydrogen.
99-429   Log #CP547  HEA-MED
(9.7.3.2)   Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise to read as follows:
9.7.3.2 Cylinder valves shall be opened and connected in accordance with the following procedure:
(1) Make certain that apparatus and cylinder valve connections and cylinder wrenches are free of foreign materials.
(2) Turn the cylinder valve outlet away from personnel. Stand to the side — not in front and not in back. Before connecting the apparatus to cylinder valve, momentarily open cylinder valve to eliminate dust.
(3) Make connection of apparatus to cylinder valve. Tighten connection nut securely with a wrench.
(4) Release the low-pressure adjustment screw of the pressure-reducing regulator completely.
(5) Slowly open cylinder valve to full open position.
(6) Slowly turn in the low-pressure adjustment screw of the pressure-reducing regulator until the proper working pressure is obtained.
(7) Open the valve to the utilization apparatus.

Substantiation: Pressure reducing regulators is the correct term. This will be 11.6.3.1 in the ROP preprint.
Committee Meeting Action: Accept

99-430   Log #CP548  HEA-MED
(9.7.4.1)   Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Revise to read as follows:
9.7.4.1 Personnel using cylinders and containers and other equipment covered in this chapter shall be familiar with the CGA Pin-Index Safety System and the CGA Diameter-Index Safety System, which are both designed to prevent utilization of the wrong gas.
Substantiation: CGA reference was added. This will be 11.6.4.1 in the ROP preprint.
Committee Meeting Action: Accept

99-431   Log #CP514  HEA-MED
(9.7.5.5)   Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Delete 9.7.5.5.
Substantiation: There is no known hazard.
Committee Meeting Action: Accept

99-432   Log #115  HEA-MED
(9.8)   Final Action: Reject

Submitter: Jack Stein, Medical Gas Specialists, Inc.
Recommendation: Revise text to read as follows:
The maintenance and record keeping (9.8) section of NFPA 99 needs to be included in the NFPA 99C. There should also be a stipulation noting the requirement applies to all levels of system.
Substantiation: Several diligent hospital engineers (P.E. deg) are unaware of the maintenance and record keeping requirements set forth in Chapter 9. The text in section 9.8 should be inserted in 99C.
Committee Meeting Action: Reject
Committee Statement: NFPA 99C is not a standard but an extracted document.
99-433     Log #136 HEA-MED  
(9.8)  
Final Action: Reject

Submitter: Jack Stein, Medical Gas Specialists, Inc.  
Recommendation: The Maintenance and Record Keeping (9.8) section of NFPA 99 needs to be included in NFPA 99C. There should also be a stipulation noting the requirement applies to all levels of system.  
Substantiation: Several diligent hospital engineers (P.E. degree) are unaware of the maintenance and record keeping requirements set forth in Chapter 9. The text in section 9.8 should be inserted in 99C.  
Committee Meeting Action: Reject  
Committee Statement: NFPA 99C is not a standard but an extracted document.

99-434     Log #CP515 HEA-MED  
(9.8)  
Final Action: Accept

Submitter: Technical Committee on Medical Equipment,  
Recommendation: Delete all of Section 9.8.  
Substantiation: The HEA-PIP committee will be adding these requirements to their chapter.  
Committee Meeting Action: Accept

99-435     Log #204 HEA-MED  
(9.9)  
Final Action: Accept

Submitter: Dale Woodin, American Society for Healthcare Engineering  
Recommendation: Delete text as follows:  
9.9 Policies and Procedures  
9.9.1 Administration authorities of healthcare organizations shall provide policies and procedures for safe practice.  
9.9.1.1 Purchase specifications shall include the following:  
(1) Specification for cylinders  
(2) Marking of cylinders, regulators, and valves  
(3) Proper connection of cylinders supplied to the facility  
9.9.1.2 Training procedures shall include the following:  
(1) Maintenance programs in accordance with the manufacturer's recommendations for the piped gas system  
(2) Use and transport of equipment and the proper handling of cylinders, containers, hand trucks, supports, and valve protection caps  
(3) Proper uses of the medical-surgical vacuum system in order to eliminate practices that reduce the system's effectiveness  
9.9.1.3 Policies for enforcement shall include the following:  
(1) Regulations for the storage and handling of cylinders and containers of oxygen and nitrous oxide  
(2) Prompt evaluation of all signal warnings and the performance of all necessary measures to re-establish the proper function of the medical gas system  
(3) The capability and resources of the organization to cope with a complete loss of any medical gas system  
(4) All tests required in 5.3.12 successfully conducted prior to the use of any medical gas piping system for patient care  
Substantiation: Section 9.9 Delete. This section Information is covered in other sections of chapter 9. Section 9.9.1.2 Delete this information, it is addressed in section 9.6.2.1 (Qualification and Training of Personnel). Section 9.9.1.3 Delete this section. It is addressed in section 9.7.1.3 (Policies for enforcement ...)
This is not original material; its reference/source is as follows:  
I am proposing this revision on behalf of the ASHE Gas Equipment Workgroup  
Committee Meeting Action: Accept
9.9.1.3 Policies for enforcement shall include the following:
(1) Regulations for the storage and handling of cylinders and containers of oxygen and nitrous oxide
(2) Prompt evaluation of all signal warnings and the performance of all necessary measures to re-establish the proper function of the medical gas system
(3) The capability and resources of the organization to cope with a complete loss of any medical gas system
(4) All tests required in 5.9.1.12 successfully conducted prior to the use of any medical gas piping system for patient care

Substantiation:  Point 4 references a level 3 system – it should reference a level 1 as the primary test (specifically 5.1.12.3)

This is not original material; its reference/source is as follows:
I am proposing this revision on behalf of the ASHE environmental safety workgroup

Committee Meeting Action:  Reject

Committee Statement:  See Committee Action on Proposal 99-435 (Log #204).
Technical Committee on Medical Equipment,

Recommendation: Add new section to read as follows:

9.10 Liquid Oxygen Equipment.

9.10.1 General. The storage and use of liquid oxygen in liquid oxygen base reservoir containers and liquid oxygen portable containers shall comply with the following, or shall be stored and used in accordance with the adopted fire prevention code.

9.10.2 Information and Instructions. The liquid oxygen seller shall provide the user with documentation that includes, but is not limited to, the following:

1. Manufacturer’s instructions including labeling for storage and use of the containers.
2. Storing and using containers away from ignition sources, exits, electrical hazards, and high temperature devices.
3. Methods for container restraint to prevent falling.
4. Requirements for container handling.
5. Safeguards for refilling of containers.

9.10.3 Container Storage, Use and Operation

9.10.3.1* Containers shall be stored, used, and operated in accordance with the manufacturer’s instructions and labeling.

9.10.3.2 Containers shall not be placed in the following areas:
1. Where they can be tipped over by the movement of a door
2. Where they interfere with foot traffic
3. Where they are subject to damage from falling objects
4. Where exposure to open flames and high-temperature devices.

9.10.3.3* Liquid oxygen base reservoir containers shall be secured by one of the following methods while in storage or use to prevent tipping over caused by contact, vibration, or seismic activity:
1. Securing to a fixed object with one or more restraints
2. Securing within a framework, stand, or assembly designed to resist container movement
3. Restrained by placing the container against two points of contact

9.10.3.4 Liquid oxygen base reservoir containers shall be transported by a cart or hand truck designed for such use unless a container is equipped with a roller base.

9.10.3.5 The transfilling of containers shall be in accordance with the manufacturer’s instructions and with the following:

9.10.3.5.1 Liquid oxygen containers shall be filled outdoors or in compliance with 9.6.2.3.1.

9.10.3.5.1.1* A drip pan compatible with liquid oxygen shall be provided under the liquid oxygen base reservoir container’s filling and vent connections used during the filling process unless the filling is performed on a non-combustible surface such as concrete.

9.10.3.5.2 Liquid oxygen portable containers shall be allowed to be filled indoors when the liquid oxygen base reservoir container is designed for filling such containers and the written instructions provided by the container manufacturer are followed.

NOTE: Move annex material to A.9.10.3.2(5)

9.10.4 Maximum Quantity. The maximum total quantity of liquid oxygen allowed in storage and in use in a patient bed location or patient care room shall be 120 L (31.6 gal) provided the patient bed location and/or patient care room are separated from the remainder of the facility by fire barriers and horizontal assemblies having a minimum fire resistance rating of 1 hour in accordance with the adopted building code.

NEW Definitions:

Liquid Oxygen Portable Container. A container used for liquid oxygen not exceeding 1.5 L (0.396 gal) specifically designed for use as a medical device as defined by 21 USC Chapter 9, the United States Food, Drug and Cosmetic Act, that is intended for portable therapeutic use and to be filled from its companion base unit, which is a liquid oxygen base reservoir container. [ROC-7]

Liquid Oxygen Base Reservoir Container. A container used for liquid oxygen not exceeding 60 L (15.8 gal) specifically designed for use as a medical device as defined by 21 USC Chapter 9, the United States Food, Drug and Cosmetic Act, that is intended to deliver gaseous oxygen for therapeutic use, transfilling or both. [ROC-7]
Substantiation: The use of in-home care type LOX equipment in healthcare facilities has become a major interest of fire code officials across the country. CGA instituted an Ad Hoc Code Committee process to address this concern in the IFC, and activity is ongoing. It will be important to harmonize NFPA 99 with the approach taken in the IFC. Inquiries from NFPA 99 to the CGA reveal that NFPA is receiving questions in this area, and more can be expected once the IFC provisions are widely distributed. NFPA and CGA should take a proactive role in this subject so that the model codes are coordinated in this regard.

This will be section 11.7 of the ROP preprint.

Committee Meeting Action: Accept

99-438 Log #CP508 HEA-MED (Chapter 10) Final Action: Accept

Submitter: Technical Committee on Medical Equipment,
Recommendation: Delete Chapter 10 in its entirety.
Substantiation: Much of Chapter 10 is redundant with Chapter 8. The common requirements were incorporated into Chapter 8.
Committee Meeting Action: Accept

99-466 Log #385a HEA-MED (13.4.1.2.8) Final Action: Accept in Principle

Submitter: Jan Ehrenwerth, Yale University School of Medicine
Recommendation: Add new text as follows:
Anesthetic Apparatus. Anesthetic apparatus shall conform to the requirements in 9.5.1. Each anesthetizing location shall be permitted one auxiliary oxygen cylinder that is not attached to the anesthesia machine. The cylinder must be properly restrained or placed in a suitable holder. The cylinder shall have a regulator and a flow metering device attached, unless these are integral to the cylinder valve. A means of opening the cylinder valve shall be kept attached to the cylinder.
Substantiation: A readily available source of auxiliary oxygen is an important safety measure in the operating. This is especially true in the case of electronic anesthesia machines where an electronic failure could result in the inability to deliver oxygen to the patient.
Committee Meeting Action: Accept in Principle
Revise to read as follows:
11.3.3.4 Individual small-size (A, B, D, or E) cylinders available for immediate use in patient care shall not be considered in storage.
Committee Statement: The existing Chapter 13 was deleted and the correct reference in the preprint is section 11.3.3.4.
17.3.9 Gas Equipment Requirements.

Gas equipment used in healthcare facilities shall conform to such requirements for patient equipment in Chapter 9 as applicable.

The use of LOX in healthcare facilities should be in accordance with current or proposed IFC section 4006.

Substantiation: The use of LOX in home care occupancies including healthcare facilities has become a major interest of fire code officials across the country. CGA instituted an Ad Hoc Code Committee process to address this concern in the IFC, and activity is ongoing. It will be important to harmonize NFPA 99 with the approach taken in the IFC. Inquiries from NFPA 99 to the CGA reveal that NFPA is receiving questions in this area, and more can be expected once the IFC provisions are widely distributed. NFPA and CGA should take a proactive role in this subject so that the model codes are coordinated in this regard.

This is not original material; its reference/source is as follows:

IFC section 4006

Committee Meeting Action: Accept in Principle

Committee Statement: See Committee Proposal 99-468 (Log #CP525).
19.3.9 Gas Equipment Requirements. Gas equipment used in the home for healthcare and healthcare facilities shall conform to such requirements of Chapter 9 as applicable.

The use of LOX in home health care and healthcare facilities should be in accordance with current or proposed IFC section 4006.

Substantiation: The use of LOX in home care occupancies including healthcare facilities has become a major interest of fire code officials across the country. CGA instituted an Ad Hoc Code Committee process to address this concern in the IFC, and activity is ongoing. It will be important to harmonize NFPA 99 with the approach taken in the IFC. Inquiries from NFPA 99 to the CGA reveal that NFPA is receiving questions in this area, and more can be expected once the IFC provisions are widely distributed. NFPA and CGA should take a proactive role in this subject so that the model codes are coordinated in this regard.

This is not original material; its reference/source is as follows:

IFC section 4006

Committee Meeting Action: Accept in Principle
Committee Statement: See Committee Proposal 99-468 (Log #CP525).

99-510 Log #411 HEA-MED (Chapter X (New)) Final Action: Reject

Submitter: Dale Woodin, ASHE-American Society for Healthcare Engineering of the American Hospital Association (AHA)

Recommendation:

***Include-99-L411***

Substantiation: Consolidation of these hazards and safety issues into one comprehensive chapter will create a “one stop shopping” approach to locating these topics within the document and in doing so dramatically improve the ease of use of the document.

This is not original material; its reference/source is as follows:
Proposing revision on behalf of the ASHE Environmental Safety Workgroup.
Committee Meeting Action: Reject
Committee Statement: This material is better suited in a manual but is not in the format that can be used in this standard. Laboratories is being deleted from this standard and it is not appropriate to add this material back in.
I. APPLICABILITY
This chapter applies to the handling, storage, and transportation of Nonflammable Medical Gas Cylinders.

II. NATURE OF HAZARDS

Fire
Oxygen and nitrous oxide, the gases normally used for relative analgesia and as components of general anesthesia, are strong oxidizing gases and individually or as a mixture supply combustion quite readily. (Reference B.6.1.1)
In an oxygen-enriched atmosphere, materials that are flammable and combustible in air ignite more easily and burn more vigorously. The materials that could be found on or near patients include hair oils, oil-based lubricants, skin lotions, clothing, linens, paper, rubber, alcohols, acetone, and some plastics. (Reference B.6.1.2)
Sources of ignition can include open flames, burning tobacco, electric heating coils, defective electrical equipment, and adiabatic heating of gases.
Sudden compression or recompression of a gas to high pressure can generate large increase in temperature [up to 1093°C (2000°F)] that can ignite any organic material present, including grease. (See also NFPA 53, Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres.) (Reference B.6.1.4)

A hazard exists if either oxygen or nitrous oxide leaks into a closed space, creating an oxygen-enriched atmosphere. (Reference B.6.1.5)
Sources of ignition include not only the usual ones in ordinary atmospheres, but others that become significant hazards in oxygen-enriched atmospheres (see B.6.1.7 and B.6.1.8) such as the following:
(1) Open flames
(2) Burning tobacco
(3) Electric radiant heaters
(4) The discharge of a cardiac defibrillator
(5) Arcing and excessive temperatures in electrical equipment
Electrically powered oxygen apparatus and electrical equipment intended for use in an oxygen-enriched atmosphere if electrical defects are present. (Reference B.6.1.14)

Mechanical.
A large amount of energy is stored in a cylinder of compressed gas. If the valve of a cylinder is struck (or strikes something else) hard enough to break off the valve, the contents of the cylinder could be discharged with sufficient force to impart dangerous reactive movement to the cylinder. (Reference B.6.3.1)
Cylinders and containers can be heavy and bulky and can cause personal injury or property damage (including to the cylinder or container) if improperly handled. In cold climates, cylinders or containers stored outdoors or in unheated ventilated rooms can become extremely cold [see 9.7.2.4(11) and 9.7.2.1(3)]. A hazardous situation could develop if these cylinders or containers are heated [see 9.7.2.4(10)] (Reference B.6.3.2)
A hazardous condition exists if cylinders or containers are improperly located so that they become overheated or tipped over. If a container is tipped over or placed on its side, liquid oxygen could be spilled. The liquid can cause frostbite on contact with skin (Reference B.6.3.4). A hazardous condition exists if there is improper labeling of cylinders or containers or inattention to the manufacturer’s label or instructions. (Reference B.6.3.5)

III. CYLINDER AND CONTAINER STORAGE REQUIREMENTS

STORAGE
Storage for nonflammable gases equal to or greater than 85 m$^3$ (3000 ft$^3$) compressed shall comply with 5.1.3.3.2 and 5.1.3.3.3 (Reference 9.4.1)
Storage for nonflammable gases greater than 8.5 m$^3$ (300 ft$^3$) but less than 85 m$^3$ (3000 ft$^3$) compressed shall comply with the requirements in 9.4.2.1 through 9.4.2.3. (Reference 9.4.2)
Storage locations shall be outdoors in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors (or gates outdoors) that can be secured against unauthorized entry. (Reference 9.4.2.1) Storage locations shall include a precautionary sign. (Reference 9.4.4)
A precautionary sign, readable from a distance of 1.5 m (5 ft), shall be displayed on each door or gate of the storage room or enclosure. (Reference 9.4.4.1) The sign shall include the following wording as a minimum (Reference 9.4.4.2):

**CAUTION**

**OXIDIZING GASES STORED WITHIN NO SMOKING**

Oxidizing gases, such as oxygen and nitrous oxide, shall not be stored with any flammable gas, liquid, or vapor. (Reference 9.4.2.2)
Oxidizing gases such as oxygen and nitrous oxide shall be separated from combustibles or materials by one of the following:
1. A minimum distance of 6.1 m (20 ft)
2. A minimum distance of 1.5 m (5 ft) if the entire storage location is protected by an automatic sprinkler system designed in accordance with NFPA 13. Standard for the Installation of Sprinkler Systems
3. An enclosed cabinet of noncombustible construction having a minimum fire protection rating of 1/2 hour. (Reference 9.4.2.3)

Cylinder and container storage locations shall meet 5.1.3.3.1.7 with respect to temperature limitations. (Reference 9.4.2.5)
Electrical fixtures in storage locations shall meet 5.1.3.3.2(5). (Reference 9.4.2.6)
Cylinder protection from mechanical shock shall meet 5.3.13.13. (Reference 9.4.2.7)
Cylinder or container restraint shall meet 5.3.13.13. (Reference 9.4.2.8)
Smoking, open flames, electric heating elements, and other sources of ignition shall be prohibited within storage locations and within 6.1 m (20 ft) of outside storage locations. (Reference 9.4.2.9)
Cylinder valve protection caps shall meet 5.3.13.13. (Reference 9.4.2.10)
Gas cylinder and liquefied gas container storage shall comply with 5.1.3.4.12 (Reference 9.4.2.11)
Storage for nonflammable gases with a total volume compressed equal to or less than 8.5 m$^3$ (300 ft$^3$) shall comply with the requirements in 9.4.3.1 and 9.4.3.2. (Reference 9.4.3)
Individual cylinder storage associated with patient care areas, not to exceed 2100 m$^2$ (22,500 ft$^2$) of floor area, shall not be required to be stored in enclosures. (Reference 9.4.3.1) ??

Precautions in handling these cylinders shall be in accordance with 9.7.2. (Reference 9.4.3.2)
When small-size (A, B, D, or E) cylinders are in use, they shall be attached to a cylinder stand or to a therapy apparatus of sufficient size to render the entire assembly stable. (Reference 9.4.3.3)
An individual cylinder placed in patient room for immediate use by a patient shall not be required to be stored in an enclosure. (Reference 9.4.3.4)

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Cylinders shall not be chained to portable or movable apparatus such as beds and oxygen tents. (Reference 9.4.3.5)

Storage shall be planned so that cylinders can be used in the order in which they are received from the supplier. (Reference 9.7.5.1) Each of the medical gas cylinders has an expiration date and is not usable after the expiration date.

If stored within the same enclosure, empty cylinders shall be segregated from full cylinders. (Reference 9.7.5.2)

Empty cylinders shall be marked to avoid confusion and delay if a full cylinder is needed in a rapid manner. (Reference 9.7.5.3)

Cylinders stored in the open shall be protected as follows:

1. Against extremes of weather and from the ground beneath to prevent rusting
2. During winter, against accumulations of ice or snow
3. In summer, screened against continuous exposure to direct rays of the sun in those localities where extreme temperatures prevail

(Reference 9.7.5.4)

**IV. TRANSPORTATION OF CYLINDER REQUIREMENTS**

**Nonpatient Gas Equipment**

Carts and hand trucks for cylinders and containers shall be constructed for the intended purpose, be self-supporting, and be provided with appropriate chains or stays to retain cylinders or containers. (Reference 9.5.3.1.1)

**Qualification and Training of Personnel** (Reference 9.6.2.1)

Personnel concerned with the application and maintenance of medical gases and others who handle medical gases and the cylinders that contain the medical gases shall be trained on the risks associated with their handling and use. (Reference 9.6.2.1.1)

The health care facilities shall provide programs of continuing education for their personnel. (Reference 9.6.2.1.2)

Continuing education programs shall include periodic review of safety guidelines and usage requirements for medical gases and the cylinders. *(See Sections B.2 and B.6)* (Reference 9.6.2.1.3)

**CYLINDER REQUIREMENTS**

Cylinders and containers shall be labeled in accordance with CGA C-7, *Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers*. Color coding shall not be utilized as a primary method of determining cylinder or container content. (Reference 9.6.3.1.6)

All labeling shall be durable and withstand cleansing or disinfection. (Reference 9.6.3.1.7)

**V. OPERATION AND MANAGEMENT OF CYLINDERS** *(Reference 9.7)*

**Administration.** Administrative authorities of health care organizations shall provide policies and procedures for safe practices. (Reference 9.7.1)

Purchase specifications shall include the following:

1. Specifications for cylinders
2. Marking of cylinders, regulators, and valves
3. Cylinders shall be permitted to be fitted with valves that include a means to slow the initial opening pressurization.
4. Training procedures shall include the following:
   1. Use and transport of equipment and the proper handling of cylinders, containers, hand trucks, supports, and valve protection caps
   2. Verify gas content and mechanical connection specificity of each cylinder or container prior to placing them into service.
   3. Annual training by the supplier on the operation of a bulk cryogenic system when provided. *(Reference 9.7.1)*
   4. Policies for enforcement shall include the following:
      1. Regulations for the storage and handling of cylinders and containers of oxygen and nitrous oxide.
      2. Oxygen cylinders, containers, and associated equipment shall be protected from contact with oil or grease. Specific precautions shall include the following:
         1. Oil, grease, or readily flammable materials shall never be permitted to come in contact with oxygen cylinders, valves, regulators, gauges, or fittings.
         2. Regulators, fittings, or gauges shall never be lubricated with oil or any other flammable substance.
         3. Oxygen cylinders or apparatus shall never be handled with oily or greasy hands, gloves, or rags.
      3. Oxygen cylinders shall be protected from damage. Specific procedures shall include the following:
         1. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.
         2. Oxygen cylinders shall not be stored near elevators, gangways, or in locations where heavy moving objects will strike them or fall on them.
         3. Cylinders shall be protected from the tampering of unauthorized individuals.
         4. Cylinders shall be supported by radiators, steam pipes, or heat ducts. *(Reference 9.7.2.3)*
         5. Oxygen fittings, valves, regulators, or gauges shall never be used for any service other than that of oxygen.
         6. Gases of any type shall never be mixed in an oxygen cylinder or any other cylinder.
         7. Oxygen shall always be dispensed from a cylinder through a pressure regulator.
         8. The cylinder valve shall be opened slowly, with the face of the indicator on the regulator pointed away from all persons.
         9. Oxygen shall be referred to by its proper name, oxygen, not air, and liquid oxygen referred to by its proper name, not liquid air.
         10. Oxygen shall never be used as a substitute for compressed air.
         11. The markings stamped on cylinders shall not be tampered with because it is against federal statutes to change these markings without written authority from the Bureau of Explosives.
         12. Markings used for the identification of contents of cylinders shall not be defaced or removed, including decals, tags, stenciled marks, and the upper half of the shipping tag.
         13. The owner of the cylinder shall be notified if any condition has occurred that might permit any foreign substance to enter a cylinder or valve, giving details and cylinder number.
99/L411/A2011/ROP/Rec
Proposed ENVIRONMENTAL SAFETY CHAPTER – Incorporate existing Chapter 11 – Laboratories (revised)

Proposed Revision: NFPA 45 should serve as the basic NFPA standard for laboratories. The ASHE Environmental Safety workgroup proposes that Chapter 11 be deleted with a small section on Laboratory Safety incorporated into the proposed new chapter on Environmental Safety. We suggest this be implemented in 2 steps

1) delete substantial sections of Chapter 11 (laboratories) which are not needed if it is agreed that NFPA 45 should be the basic standard for laboratories.
2) incorporate the remaining, healthcare specific, sections of Chapter 11 into the new chapter (eliminating chapter 11)

Step 1
DELETE:

11.1.1. Criteria to minimize the hazards of fire or explosions
11.1.2. Fire protection and non-fire health hazards
11.1.4. Applicability to buildings and portions of buildings devoted to lab usage.
11.2. Nature of hazards (no content)
11.2.1. Fire loss prevention (no content)
11.2.1.1 Evaluation of hazards
11.2.1.1.2 Periodic review of operations
11.2.1.1.3 Unattended operations
11.2.1.2 Fire prevention procedures
11.2.1.3 Construction and Arrangement (Delete entire section)
11.3.1 Lab corridors for transporting of patients in beds
11.3.3 Exhaust air
11.3.4 Ventilation
11.3.5 Fume hoods
11.4.1 Equipment, general
11.5 Fire Protection (Delete entire section)
11.7.1 Flammable & combustible liquids, general
11.7.2.1 Used from & stored in approved containers
11.7.2.3.4 Storage areas in accordance with NFPA 30
11.7.3 Transfer of flammable or combustible liquids in accordance with NFPA 30
11.9 Transfer of Gases (To be handled by Gas Equipment work group)
11.10 Laboratory Gas Cylinder Storage (To be handled by Gas Equipment work group)
11.11 Piped Gas Systems (To be handled by Medical Gas Distribution work group)

STEP 2
I. APPLICABILITY
This chapter establishes criteria to minimize the hazards of fire and explosions as well as address non-fire safety issues in clinical laboratories in health care occupancies.

(NFPA 99.11.1.3) NFPA 45, Standard on Fire Protection for Laboratories using Chemicals, is the basic NFPA standard for laboratories that covers the construction, ventilation systems, and related fire protection of all laboratories in all facilities. However, this chapter has more stringent requirements for laboratories located in health care facilities.

II. CLASSIFICATION
Quantities of flammable and combustible liquids in laboratories in health care occupancies shall not exceed the requirements for Class D laboratories as reflected in Table XXX.

(include Class D portion of Tables 2.2.1 (a) and 2.2.1 (b) from NFPA 45)

III. FIRE PREVENTION
(NFPA 45: 4.6, modified) Fire prevention procedures shall be established. Certain critical areas shall require special consideration, including but not limited to the following:

1) Handling and storage of chemicals, flammable and combustible liquids, and gases
2) Open flame and spark-producing equipment work permit system for construction/renovation/repair activities by internal staff or external contractors.
3) Arrangements and use of portable electric cords
4) Non-smoking policy

IV. EXIT DETAILS
(NFPA 99: 11.3.2.1) Any room arranged for laboratory work that has an area in excess of 92.9 m<sup>2</sup> (1000 ft<sup>2</sup>) shall have at least two exit access doors remote from each other, one of which shall open directly onto a means of egress.

(NFPA 99: 11.3.2.2) A second means of access to an exit shall be provided for any laboratory work areas in which hazards exist as required by 3.4.1 of NFPA 45, Standard on Fire Protection for Laboratories using Chemicals.

(NFPA 99: 11.3.2.3) Travel distance between any point in a laboratory unit and an exit access door shall not exceed 22.9 m (75 ft).

(NFPA 99: 11.3.2.4) Exit access doors from laboratories shall meet the requirements of NFPA 101, Life Safety Code.

(NFPA 99: 11.3.2.5) Laboratory corridors constituting access to an exit shall meet the requirements of NFPA 101, Life Safety Code.

(NFPA 99: 11.3.2.6) Corridors shall be maintained clear and unobstructed at all times.

V. CHEMICALS
(NFPA 45: 7.1) When a chemical is ordered, steps shall be taken to determine its hazards and to transmit that information to those who will received, store, use, or dispose of the chemical. Restrictions imposed by governmental regulations and in-house rules shall be followed.

(NFPA 45: 9.1.1.1) Before laboratory tests or chemical reactions are begun, evaluations shall be made for hazards that can be encountered or generated during the course of the work. Evaluations shall include the hazards associated with the properties and the reactivity of the materials used and any immediate and end products that can be formed, hazards associated with the operation of the equipment at the operating conditions, and hazards associated with the proposed reactions.
(NFPA 99: 11.7.2.1) Flammable and combustible liquids shall be used from and stored in approved containers in accordance with NFPA 30, Flammable and Combustible Liquids Code, and NFPA 45, Standard on Fire Protection for Laboratories Using Chemicals.

(NFPA 99: 11.7.2.2) Storage cabinets for flammable and combustible liquids shall be constructed in accordance with Section 4.3 of NFPA 30, Flammable and Combustible Liquids Code.

(NFPA 99: 11.7.2.3) In laboratories not classified by the authority having jurisdiction as very small work areas, established laboratory practice shall limit working supplies of flammable or combustible liquids.

(NFPA 99: 11.7.2.3.1) The total volume of class I, II, and IIIA liquids outside of approved storage cabinets and safety cans shall not exceed 3.78 L (1 gal) per 9.29 m<sup>2</sup>/sup> (<sup>2</sup>100 ft<sup>2</sup>).

(NFPA 99: 11.7.2.3.2) The total volume of Class I, II, and IIIA liquids including those contained in approved storage cabinets and safety cans shall not exceed 7.57 L (2 gal) per 9.29 m<sup>2</sup>/sup> (<sup>2</sup>100 ft<sup>2</sup>).

(NFPA 99: 11.7.2.3.3) No flammable or combustible liquid shall be stored or transferred from one vessel to another in any exit access corridor or passageway leading to an exit.

(NFPA 45: 7.2.3.1) Hazardous chemicals stored in the open shall be kept to the minimum necessary for the work being done.

(NFPA 45: 7.2.3.2) Container types and maximum capacities shall comply with Table YYY. (Insert Table 7.2.3.2 from NFPA 45.)

Exception No. 1: Glass containers as large as 4 L (1.1 gal) shall be permitted to be used if needed and if the required purity would be adversely affected by storage in a metal or an approved plastic container, or if the liquid would cause excessive corrosion or degradation of a metal or an approved plastic container.

Exception No. 2: Containers of not more than 227 L (60 gal) capacity shall be permitted in a separate area inside the building if the inside area meets the requirements of NFPA 30, Flammable and Combustible Liquids Code.

(NFPA 45: 7.2.3.3) Chemical inventories shall be maintained within the prescribed capacities of the storage facility.

(NFPA 45: 7.2.3.4) Incompatible materials shall be segregated to prevent accidental contact with one another.

(NFPA 45: 7.2.3.5) Containers of materials that might become hazardous during prolonged storage shall be dated when first opened. At the end of 6 months, the material shall be evaluated or tested for continued safe use. Material that is found to be safe or that can be treated to be made safe shall be permitted to be redated and retained for an additional 6-month period. All other material shall be safely discarded.

(NFPA 45: 7.2.3.6) Storage cabinets used in laboratories shall not be required to be vented for fire protection purposes.

(NFPA 45: 7.2.3.7) Laboratory storage facilities shall be inspected to ensure compliance with NFPA 45, Standard for Laboratories Using Chemicals, chapter 7.

(NFPA 99: 11.7.4.1) Flammable liquids and combustible liquids with flash points lower than 93.3°C (200°F) (Class I, II, and IIIA liquids) shall be heated in hoods or with special local exhaust ventilation if the quantities exceed 10 mL or if the liquid is heated to within 16.6°C (30°F) of the flash point of the liquid.

(NFPA 99: 11.7.4.2.1) Flammable or combustible liquids shall be heated with hot water, steam, or an electric mantle, depending on their boiling points.

(NFPA 45: 4.6.1 modified) Open flames shall not be employed for heating chemicals.

(NFPA 45: 7.2.2.1) Receiving, transporting, unpacking, and dispensing of chemicals and other hazardous materials shall be carried out by trained personnel in such locations and areas as to minimize hazards from flammable, reactive, or toxic materials.

(NFPA 45: 7.2.2.4) Before a chemical material is used, the user shall determine that the information and facilities are available for safe disposal of hazardous materials and waste products.

(NFPA 45: 7.2.2.6) Transfer of Class I liquids to smaller containers from bulk stock containers not exceeding 19 L (5 gal) in capacity shall be performed as follows:

(1) In a laboratory hood
(2) In an area provided with ventilation adequate to prevent accumulations of flammable vapor/air mixtures from exceeding 25 percent of the lower flammable limit
(3) Inside liquid storage areas specifically designed and protected for dispensing Class I flammable liquids that meet the requirements of NFPA 30, Flammable and Combustible Liquids Code.

(NFPA 45: 7.2.2.7) Transfer of Class I liquids from containers of 19 L (5 gal) or more capacity shall be carried out as follows in (1) or (2):

(1) In a separate area outside the building
(2) Inside liquid storage areas specifically designed and protected for dispensing Class I flammable liquids that meet the requirements of NFPA 30, Flammable and Combustible Liquids Code.

(NFPA 45: 7.2.2.8) Class I liquids shall not be transferred between conductive containers of greater than 4 L (1.1 gal) capacity unless the containers are electrically interconnected by direct bonding or by indirect bonding through a common grounding system. When dispensing Class I liquids involves nonconductive containers larger than 4 L (1.1 gal), which can be difficult to Bond or ground, special dispensing procedures commensurate with the electrical characteristics of the liquid shall be developed and implemented.

(NFPA 99: 11.7.5) Disposal of hazardous materials shall be accomplished off the premises by a disposal specialist or at a safe location away from the health care facility by competent personnel using procedures established in concurrence with the authority having jurisdiction.

VI. EMERGENCY PROCEDURES

(NFPA 45: 4.6.1 modified) Fire prevention procedures shall be established. Certain critical areas shall require special consideration, including but not limited to the following:

(1) Handling and storage of chemicals, flammable and combustible liquids, and gases
(2) Open flame and spark-producing equipment work permit systems
(3) Arrangements and use of portable electric cords
(4) Emergency procedures shall be established for controlling chemical spills.

VII. EQUIPMENT EMPLOYING LIQUIDS

(NFPA 45: 4.6.1.1) Tissue processors and similar automatic equipment that release ignitable (flammable or combustible) vapors into the ambient workspace shall be operated at least 1.52 m (5 ft) from the storage of combustible materials, unless separated by 1-hour fire-resistant construction.

(NFPA 45: 4.6.1.2) All new tissue processors and similar automatic equipment that release ignitable vapors shall be provided with the following safeguards and interlocks as part of a monitored audible and visual alarm:

(1) Low liquid level
(2) High vapor

(NFPA 45: 4.6.1.2.1) The safeguards above shall be connected to an audible alarm in a constantly attended location.

(NFPA 45: 4.6.1.2.2) Unattended laboratory operations employing flammable or combustible reagents shall be conducted in an area equipped with an automatic fire extinguishing system.

(NFPA 45: 9.1.1) Unattended or automatic laboratory operations involving hazardous chemicals shall be provided with regular surveillance for abnormal conditions.

(NFPA 45: 9.1.2.1) All heating of flammable or combustible liquids shall be conducted so as to minimize fire hazards.
VII. SAFETY EQUIPMENT

(NFPA 99: 11.6) Where the eyes or body of any person can be exposed to injurious corrosive materials, suitable fixed facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use.

See the section on eye washes and showers in the Environmental Safety Chapter for further information.

See NFPA 45: 6 for information on laboratory hoods.

VIII. SAFETY

(NFPA 99: 11.8.1.1) A safety officer shall be appointed to supervise safe practices in the laboratory.

The safety officer shall also fulfill the responsibilities of the Chemical Hygiene Officer as required in the OSHA standard, 29CFR, 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*.

(NFPA 99: 11.8.1.2) These responsibilities shall be in addition to surveillance of hazards attendant to the following:

1. Caustics
2. Corrosives
3. Compressed gases
4. Electrical installations
5. Other hazards indigenous to laboratories in health care facilities

(NFPA 99: 11.8.1.2.2) The laboratory safety officer shall supervise operations and equipment related to safe operations and practices, including such items as the following:

1. Ventilating provisions
2. Fire protection apparatus
3. Periodic flushing of sinks, emergency showers, and eye wash units
4. Shelf stocks and storage of flammable and combustible materials and caustic and corrosive liquids shall be reviewed at appropriate, regular intervals.
5. Aggregate quantities of hazardous materials exceeding 91 kg (200 lb), or flammable liquids exceeding 38 L (10 gal)
6. Dry hazardous chemicals in containers in excess of 2.27 kg (5 lb)
7. Compressed gases or cryogenic liquids in containers that are greater than 12.7 cm (5 in) in length

(NFPA 99: 11.2.1.1.1) Responsibilities shall include ensuring that the equipment and preparation for fire fighting are appropriate for the special fire hazards present.

(NFPA 99: 11.8.1.1.1) Responsibilities shall include ensuring that the equipment and preparation for fire fighting are appropriate for the special fire hazards present.

(NFPA 99: 11.8.1.1.4 modified) The laboratory safety officer shall prepare and supervise the proper maintenance of safety documentation that can be preserved for the record.

(NFPA 99: 11.8.1.2.1 modified) A system of prompt reporting of defective equipment and its prompt repair shall be implemented.

(NFPA 99: 11.8.1.2.2) Periodic inspection shall be made of all electrical and gas equipment.

(NFPA 99: 11.8.1.4) There shall be a written procedure for the disposal of hazardous waste in accordance with local, state, and federal hazardous material and waste regulation.

(NFPA 99: 11.8.1.3) The safety officer shall also have oversight of the periodic education of laboratory personnel including the following:

1. New employee orientation
2. The nature of combustible and flammable liquids and gases
3. First aid
4. Fire fighting
5. The use of protective equipment
6. Observation and reporting of unsafe conditions

(NFPA 99: 11.2.1.4 modified) New laboratory personnel shall be instructed in general safety practices for the laboratory and specific safety practices for the equipment, chemicals, and procedures they will use.

(NFPA 99: 11.2.1.1.1) Responsibilities shall include ensuring that the equipment and preparation for fire fighting are appropriate for the special fire hazards present.

(NFPA 99: 11.8.1.1.2 modified) Continuing safety education and supervision shall be provided.

(NFPA 99: 11.2.1.4.2 modified) Laboratory procedures shall be reviewed annually.

(NFPA 99: 11.2.1.4.3) Fire exit drills shall be conducted at least quarterly.

(NFPA 99: 11.2.1.4.4) Fire exit drills shall be arranged so that each person shall be included at least annually.

X. IDENTIFICATION OF HAZARDS

(NFPA 99: 11.8.2.1 modified) All doors leading to laboratories in health care facilities shall be marked with signage indicating the fire hazards of materials when significant quantities, as defined below, are intended to be used within the area.

(NFPA 99: 11.8.2.2) For signage purposes, "significant quantities" in an area shall include any of the following:

1. Hazardous materials in glass containers that are 3.8 L (1 gal) in size or larger.
2. Compressed gases or cryogenic liquids in containers that are greater than 12.7 cm (5 in) in length
3. Dry hazardous chemicals in containers in excess of 2.27 kg (5 lb)
4. Aggregate quantities of hazardous materials exceeding 91 kg (200 lb), or flammable liquids exceeding 38 L (10 gal)
5. All doors leading to laboratories, laboratory work areas, and laboratory storage areas shall be identified with signs to warn emergency response personnel of unusual or severe hazards that are not directly related to the fire hazards of contents.

(NFPA 99: 11.8.2.4) It shall be the responsibility of the laboratory safety officer to ensure periodically that the signage properly indicates the nature of the materials being used within the identified space.

(NFPA 99: 11.8.2.5) It shall be the duty of the senior person responsible for activities in respective laboratory areas to inform the laboratory safety officer of changes in protocol and procedures that involve variations in the fire and associated hazards of materials used in individual spaces.

(NFPA 45: 10.1 modified) The hazards in the laboratory shall be communicated in the plans for fire fighting.

(NFPA 45: 10.3.1) Content identification, including precautionary information, shall be provided directly on all original and subsequent containers of hazardous chemicals, in accordance with OSHA requirements in 29CFR, 1910.1200, Hazard Communication Plan and 29CFR, 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*.

(NFPA 45: 10.3.2 modified) Containers of materials shall be dated when first opened.

DELETE from existing Chapter 11:
11.1.1. Criteria to minimize the hazards of fire or explosions
11.1.2. Fire protection and non-fire health hazards
11.1.4. Applicability to buildings and portions of buildings devoted to lab usage.
11.2. Nature of hazards (no content)
11.2.1. Fire loss prevention (no content)
11.2.1.1 Evaluation of hazards
11.2.1.2. Periodic review of operations
11.2.1.3 Unattended operations
11.2.1.2. Fire prevention procedures
11.3.1 Construction and Arrangement (Delete entire section)
11.3.2.7 Lab corridors for transporting of patients in beds
11.3.3 Exhaust air
11.3.4 Ventilation
11.3.5 Fume hoods
11.4.1 Equipment, general
11.5 Fire Protection (Delete entire section)
11.7.1 Flammable & combustible liquids, general
11.7.2.1 Used from & stored in approved containers
11.7.2.3.4 Storage areas in accordance with NFPA 30
11.7.3 Transfer of flammable or combustible liquids in accordance with NFPA 30
11.9 Transfer of Gases (To be handled by Gas Equipment work group)
11.10 Laboratory Gas Cylinder Storage (To be handled by Gas Equipment work group)
11.11 Piped Gas Systems (To be handled by Medical Gas Distribution work group)

Additional Workgroup Comments on material in Chapter 11

1. There is some confusion within the documents about which is document is primary for laboratories within healthcare facilities.

- NFPA 99: 11.1.3 Says that 45 is basic reference, but chapter 11 has more stringent requirements for labs in healthcare facilities
- NFPA 99: 11.2.1.1.3 calls for unattended operations and automatic lab equipment to be monitored periodically. This corresponds to NFPA 45: 9.1.1.4, which also adds override controls and automatic shut downs. This could be deferred to NFPA 45:
- NFPA 45 has some unique information on fire prevention and emergency plans.
- NFPA 99: 11.3.2.6 calls for clear and unobstructed corridors.
- NFPA 99: 11.4.1.4.3 Quarterly fire exit drills
- NFPA 99: 11.4.1.4.4 Each person participates in fire drills annually

I recommend deferring to 45 for hazardous assessment per the tables.

2. NFPA 45 divides laboratories into fire hazard classifications based on the type and quantity of chemicals used and whether or not the lab is sprinkled. This is found in Tables 2.2.1(a & b).

NFPA 99: 11.2.1.1.1 bases hazard assessment on the properties of the chemicals being used, the operation of the equipment, and the nature of the reactions. Section 11.5 on fire protection refers to the NFPA 45 tables to determine appropriate separation.

I recommend deferring to 45 for hazard assessment per the tables.

3. NFPA 99: 11.2.1.1.3 calls for unattended operations and automatic lab equipment to be monitored periodically. This corresponds to NFPA 45: 9.1.1.4, which also adds override controls and automatic shut downs. This could be deferred to NFPA 45.

4. The following are mostly unique to NFPA 99, chapter 11:

- NFPA 99: 11.2.1.3.3. Emergency procedures for chemical spills.
- NFPA 99: 11.2.1.3.4. Emergency procedures for extinguishing clothing fires (but the annex material for 45:4.6.3.1(5) and that for 11.2.1.3.4 are nearly identical.)
- NFPA 99: 11.2.1.4. Orientation and training

I think that we should defer to 45 in this area, but don't think that we want to get into a work permit system for Bunsen burners. Also, I think that we should ADD A SECTION ON SMOKING POLICIES in Environmental Safety.

5. NFPA 45 has some unique information on fire prevention and emergency plans.

- NFPA 45: 4.6. Fire Prevention
  - 4.6.1. Procedures
    (1) Chemicals, flammable, combustible liquids
    (2) Open flame & spark producing equipment - work permit system
    (3) Arrangement & use of portable electric cords
    (4) Smoking area controls

I would say that we can mostly defer to 45 in this area, but don't think that we want to get into a work permit system for Bunsen burners. Also, I think that we should ADD A SECTION ON SMOKING POLICIES in Environmental Safety

6. NFPA 45 defers to 101 for life safety requirements in a health care occupancy, which is fine if we decide to make this the basic document.

7. NFPA 99: 11.3.2. Exit Details

- NFPA 99: 11.3.2.2 defers to 45:3.4.1 for exit access when hazards are present, such as hoods, compressed gas cylinders, cryogenic containers, etc.
- NFPA 99: 11.3.2.6 calls for clear and unobstructed corridors.

I think that we should defer to 45 for the former, and address the issues of the latter (actually in all areas of the health care facility) in 99.

8. NFPA 45 has a good discussion of lab hoods in chapter 6. I think we should stick with that. The annex also cross references ANSI/AIHA Z9.5 on lab ventilation.

9. NFPA 99: 11.4 Equipment Employing Liquids

- NFPA 99: 11.4.1.2: Tissue processor placement away from combustible materials. (But Annex A says this is N/A for closed system processors.)
- NFPA 99: 11.4.2.1. Low level liquid and hi vapor alarms
- NFPA 99: 11.4.2.1.2. Audible alarms
- NFPA 99: 11.4.2.2. Allows unattended operations in sprinkled areas only

This is pretty specific to one piece of lab equipment. It is not duplicated in 45, so perhaps we should keep it in 99.

10. NFPA 99: 11.6. Emergency Shower (within work area)

- NFPA 99: 11.6.1 Fixed Eye Baths
  - 11.6.2. Valve configuration
  - 11.6.3. Portable eyewash does not replace fixed. More in Annex A.

99/L411/A2011/ROP/Rec

6
A.11.6. Test showers & eyewash and flush drains
I believe that this should remain in our environmental safety chapter and can be expanded to other areas within the organization.

11. NFPA 99: 11.7. Flammable and Combustible Liquids
- 11.7.2. Storage and use of flammable cabinets
- 11.7.5. Disposal of hazmat off site by disposal specialist or safe location away from health care facility by competent personnel.

NFPA 45: Chapter 7: Chemical Storage, Handling, Waste Disposal.
- 7.1. Ordering Procedures. "When a chemical is ordered, steps shall be taken to determine its hazards and to transmit that information to those who will receive, store, use, or dispose of the chemical. Restrictions imposed by governmental regulations and in-house rules shall be followed:
- Contrast with NFPA 99: A.11.1.1. "Before a hazardous chemical is ordered, controls should be established to ensure that adequate facilities and procedures are available for receiving, storing, using, and disposing of the material." It then refers to NFPA 49 and NFPA 325.

I think that 99 should hold on all of the above, but should add the governmental regulations and cross reference OSHA's Hazard Communication Standard. NFPA 45 should be the source for handling and storage, plus there is annex material at A.7.1 and A.7.2.2.1 on controls and transportation routes, respectively.

- 11.8.1.1. Requires safety officer. Annex says this may be the same safety officer for the facility. We should also reference OSHA *Occupational Exposure to Hazardous Chemicals in Laboratories*, which requires a Chemical Hygiene Officer.

The following are responsibilities of the safety officer:
- 11.8.1.1.1. Equipment and preparation for fire fighting
- 11.8.1.1.2. Various chemical hazards
- 11.8.1.1.3. Periodic education of lab personnel.
- 11.8.1.1.4. Safety Checklist

In addition:
- 11.8.1.2 Safety supervision
- 11.8.1.2.1. Reporting of defective equipment and prompt repair
- 11.8.1.2.2. Periodic inspection of electric and gas equipment
- 11.8.1.3. Inspection & testing of showers, eye washes, & emergency equipment.

All of the above is important for health care and not repeated in 45. I think we should incorporate it and perhaps expand on the facility Safety Officer.

13. NFPA 45, chapter 8. Compressed & Liquefied Gases
- Section 8.1. Cylinders
- Section 8.2. Storage and Piping

These sections should be addressed by the Gas Equipment and Medical Gas workgroups.

- Signage is addressed in 11.8.2.1-11.8.2.4. This should be retained.


I'd like to have this reviewed by the gas equipment workgroup, but 99 bases the quantity on a working supply. It then goes to NFPA 48, chapter 8 for maximum quantity permitted.

17. NFPA 99: 11.11. Piped Gas Systems
- 11.11.1. Source (manifold)
- 11.11.2. Distribution (piped)
- 11.11.3. Piped vacuum

These sections should be addressed by the Gas Equipment and Medical Gas workgroups.

18. NFPA 45. The following sections are primarily unique to 45 and 99 should defer.
- 45: 8.4. Cryogenic Fluids (There is annex material in 99 at A.11.2.6)
- 45: 9.1.2 Heating Operations (More information than 99: 11.7.4.2)
- 45: 9.1.3. Distillation operations.
- 45: 9.2.2. Refrigeration and Cooling equipment (But there is information on walk-in refrigerators in 99: A.11.7.2.6)
- 45: 9.2.3: Heating Equipment
- 45: 9.2.4: Constant Temperature Baths
- 45: 9.2.5: Electric Motors
- 45: 9.2.6: Pressure Equipment

- 10.1. Include in fire fighting plans
- 10.2. Label exhaust for hazmat. See A.10.2
- 10.3. Labeling containers

10.3.1. Cross reference OSHA Hazard Communication
10.3.2: Date opened on bottles

NFPA 45 should be the source for this material.

Attachment C

Proposed ENVIRONMENTAL SAFETY CHAPTER:
Select Parts of Existing Chapter 5 – Gas and Vacuum Systems

Workgroup Recommendation to move gas cylinder and storage from Chapter 5 to the Environmental Safety Chapter

GAS CYLINDER HANDLING AND STORAGE

I. APPLICABILITY
This chapter applies to the handling, storage, and transportation of Nonflammable Medical Gas Cylinders.

II. NATURE OF HAZARDS
Fire
Oxygen and nitrous oxide, the gases normally used for relative analgesia and as components of general anesthesia, are strong oxidizing gases and individually or as a mixture support combustion quite readily. (Reference B.6.1.1)

In an oxygen-enriched atmosphere, materials that are flammable and combustible in air ignite more easily and burn more vigorously. The materials that could be found on or near patients include hair oils, oil-based lubricants, skin lotions, clothing, linens, paper, rubber, alcohols, acetone, and some plastics. (Reference B.6.1.2)

Sources of ignition can include open flames, burning tobacco, electric heating coils, defective electrical equipment, and adiabatic heating of gases. Sudden compression or recompression of a gas to high pressure can generate large increase in temperature (up to 1093°C (2000°F)) that can ignite any organic material present, including grease. (See also NFPA 53, Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres.) (Reference B.6.1.4)

A hazard exists if either oxygen or nitrous oxide leaks into a closed space, creating an oxygen-enriched atmosphere. (Reference B.6.1.5)

Sources of ignition include not only the usual ones in ordinary atmospheres, but others that become significant hazards in oxygen-enriched atmospheres (see B.6.1.7 and B.6.1.8) such as the following:

1. Open flames
2. Burning tobacco
3. Electric radiant heaters
4. The discharge of a cardiac defibrillator
5. Arcing and excessive temperatures in electrical equipment

Electrically powered oxygen apparatus and electrical equipment intended for use in an oxygen-enriched atmosphere if electrical defects are present. (Reference B.6.1.14)

Mechanical.
A large amount of energy is stored in a cylinder of compressed gas. If the valve of a cylinder is struck (or strikes something else) hard enough to break off the valve, the contents of the cylinder could be discharged with sufficient force to impart dangerous reactive movement to the cylinder. (Reference B.6.3.1)

Cylinders and containers can be heavy and bulky and can cause personal injury or property damage (including to the cylinder or container) if improperly handled. In cold climates, cylinders or containers stored outdoors or in unheated ventilated rooms can become extremely cold (see 9.7.2.4(11) and 9.7.2.1(3)). A hazardous situation could develop if these cylinders or containers are heated (see 9.7.2.4(10)). (Reference B.6.3.2)

A hazardous condition exists if cylinders or containers are improperly located so that they become overheated or tipped over. If a container is tipped over or placed on its side, liquid oxygen could be spilled. The liquid can cause frostbite on contact with skin (Reference B.6.3.4).

A hazardous condition exists if there is improper labeling of cylinders or containers or inattention to the manufacturer’s label or instructions. (Reference B.6.3.5)

III. CYLINDER AND CONTAINER STORAGE REQUIREMENTS

STORAGE
Storage for nonflammable gases equal to or greater than 85 m³ (3000 ft³) compressed shall comply with 5.1.3.3.2 and 5.1.3.3.3. (Reference 9.4.1)

Storage for nonflammable gases greater than 8.5 m³ (300 ft³) but less than 85 m³ (3000 ft³) compressed shall comply with the requirements in 9.4.2.1 through 9.4.2.3 (Reference 9.4.2).

Storage locations shall be outdoors in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors (or gates outdoors) that can be secured against unauthorized entry. (Reference 9.4.2.1) Storage locations shall include a precautionary sign. (Reference 9.4.4)

A precautionary sign, readable from a distance of 1.5 m (5 ft), shall be displayed on each door or gate of the storage room or enclosure. (Reference 9.4.4.1) The sign shall include the following wording as a minimum (Reference 9.4.4.2):

CAUTION

OXIDIZING GASES! STORED WITHIN
NO SMOKING

Oxidizing gases, such as oxygen and nitrous oxide, shall not be stored with any flammable gas, liquid, or vapor. (Reference 9.4.2.2)

Oxidizing gases such as oxygen and nitrous oxide shall be separated from combustibles or materials by one of the following:

1. A minimum distance of 6.1 m (20 ft)
2. A minimum distance of 1.5 m (5 ft) if the entire storage location is protected by an automatic sprinkler system designed in accordance with NFPA 13, Standard for the Installation of Sprinkler Systems (Reference 9.4.2.3)
3. An enclosed cabinet of noncombustible construction having a minimum fire protection rating of 1/2 hour. (Reference 9.4.2.3)

Cylinder and container storage locations shall meet 5.1.3.3.1.7 with respect to temperature limitations. (Reference 9.4.2.5)

Electrical fixtures in storage locations shall meet 5.1.3.3.2(5). (Reference 9.4.2.6)

Cylinder protection from mechanical shock shall meet 5.3.13.1.3. (Reference 9.4.2.7)

Cylinder or container restraint shall meet 5.3.13.1.3. (Reference 9.4.2.8)

Smoking, open flames, electric heating elements, and other sources of ignition shall be prohibited within storage locations and within 6.1 m (20 ft) of outside storage locations. (Reference 9.4.2.9)

Cylinder valve protection caps shall meet 5.3.13.1.3. (Reference 9.4.2.10)

Gas cylinder and liquefied gas container storage shall comply with 5.1.3.4.12. (Reference 9.4.2.11)

Storage for nonflammable gases with a total volume compressed equal to or less than 8.5 m³ (300 ft³) shall comply with the requirements in 9.4.3.1 and 9.4.3.2. (Reference 9.4.3)

Individual cylinder storage associated with patient care areas, not to exceed 2100 m³ (22,500 ft³) of floor area, shall not be required to be stored in enclosures. (Reference 9.4.3.1)

Precautions in handling these cylinders shall be in accordance with 9.7.2. (Reference 9.4.3.2)

When small-size (A, B, D, or E) cylinders are in use, they shall be attached to a cylinder stand or to a therapy apparatus of sufficient size to render the entire assembly stable. (Reference 9.4.3.3)

An individual cylinder placed in patient room for immediate use by a patient shall not be required to be stored in an enclosure. (Reference 9.4.3.4)

Cylinders shall not be chained to portable or movable apparatus such as beds and oxygen tents. (Reference 9.4.3.5)

Storage shall be planned so that cylinders can be used in the order in which they are received from the supplier. (Reference 9.7.5.1)

If stored within the same enclosure, empty cylinders shall be segregated from full cylinders. (Reference 9.7.5.2)

Empty cylinders shall be marked to avoid confusion and delay if a full cylinder is needed in a rapid manner. (Reference 9.7.5.3)

Cylinders stored in the open shall be protected as follows:

1. Against extremes of weather and from the ground beneath to prevent rusting
2. During winter, against accumulations of ice or snow
3. In summer, screened against continuous exposure to direct rays of the sun in those localities where extreme temperatures prevail (Reference 9.7.5.4)
IV. TRANSPORTATION OF CYLINDER REQUIREMENTS

Nonpatient Gas Equipment

Carts and hand trucks for cylinders and containers shall be constructed for the intended purpose, be self-supporting, and be provided with appropriate chains or stays to retain cylinders or containers. (Reference 9.5.3.1.1)

Qualification and Training of Personnel (Reference 9.6.2.1)

Personnel concerned with the application and maintenance of medical gases and others who handle medical gases and the cylinders that contain the medical gases shall be trained on the risks associated with their handling and use. (Reference 9.6.2.1.1)

The health care facilities shall provide programs of continuing education for their personnel. (Reference 9.6.2.1.2)

Continuing education programs shall include periodic review of safety guidelines and usage requirements for medical gases and the cylinders. (See Sections B.2 and B.6) (Reference 9.6.2.1.3)

V. CYLINDER REQUIREMENTS

Cylinders and containers shall be labeled in accordance with CGA C-7, Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers. Color coding shall not be utilized as a primary method of determining cylinder or container content. (Reference 9.6.3.1.6)

All labeling shall be durable and withstand cleansing or disinfection. (Reference 9.6.3.1.7)

V. OPERATION AND MANAGEMENT OF CYLINDERS (Reference 9.7)

Administration. Administrative authorities of health care organizations shall provide policies and procedures for safe practices. (Reference 9.7.1)

Purchase specifications shall include the following:

1. Specifications for cylinders
2. Marking of cylinders, regulators, and valves
3. Cylinders shall be permitted to be fitted with valves that include a means to slow the initial opening pressurization. (Reference 9.7.1.1)

Training procedures shall include the following:

1. Use and transport of equipment and the proper handling of cylinders, containers, hand trucks, supports, and valve protection caps
2. Verify gas content and mechanical connection specificity of each cylinder or container prior to placing them into service.
3. Annual training by the supplier on the operation of a bulk cryogenic system when provided. (Reference 9.7.1.2)

Policies for enforcement shall include the following:

1. Regulations for the storage and handling of cylinders and containers of oxygen and nitrous oxide (Reference 9.7.1.3)

Oxygen cylinders, containers, and associated equipment shall be protected from contact with oil or grease. Specific precautions shall include the following:

1. Oil, grease, or readily flammable materials shall never be permitted to come in contact with oxygen cylinders, valves, regulators, gauges, or fittings.
2. Regulators, fittings, or gauges shall never be lubricated with oil or any other flammable substance.
3. Oxygen cylinders or apparatus shall never be handled with oily or greasy hands, gloves, or rags. (Reference 9.7.2.1)

Cylinders shall be protected from damage. Specific procedures shall include the following:

1. Oxygen cylinders shall be protected from abnormal mechanical shock, which is liable to damage the cylinder, valve, or safety device.
2. Oxygen cylinders shall not be stored near elevators, gangways, or in locations where heavy moving objects will strike them or fall on them.
3. Cylinders shall be protected from the tampering of unauthorized individuals.
4. Cylinders or cylinder valves shall not be repaired, painted, or altered.
5. Safety relief devices in valves or cylinders shall never be tampered with.
6. Valve outlets clogged with ice shall be thawed with warm — not boiling — water.
7. A torch flame shall never be permitted under any circumstances to come in contact with cylinder valves or safety devices.
8. Sparks and flame shall be kept away from cylinders.
9. Even if they are considered to be empty, cylinders shall never be used as rollers, supports, or for any purpose other than that for which the supplier intended them.
10. Large cylinders (exceeding size E) and containers larger than 45 kg (100 lb) weight shall be transported on a proper hand truck or cart complying with 9.5.3.1.
11. Freestanding cylinders shall be properly chained or supported in a proper cylinder stand or cart.
12. Cylinders shall not be supported by radiators, steam pipes, or heat ducts. (Reference 9.7.2.2.3)

Cylinders and their contents shall be handled with care. Specific procedures shall include the following:

1. Oxygen fittings, valves, regulators, or gauges shall never be used for any service other than that of oxygen.
2. Gases of any type shall never be mixed in an oxygen cylinder or any other cylinder.
3. Oxygen shall always be dispensed from a cylinder through a pressure regulator.
4. The cylinder valve shall be opened slowly, with the face of the indicator on the regulator pointed away from all persons.
5. Oxygen shall be referred to by its proper name, oxygen, not air, and liquid oxygen referred to by its proper name, not liquid air.
6. Oxygen shall never be used as a substitute for compressed air.
7. The markings stamped on cylinders shall not be tampered with because it is against federal statutes to change these markings without written authority from the Bureau of Explosives.
8. Markings used for the identification of contents of cylinders shall not be defaced or removed, including decals, tags, stenciled marks, and the upper half of the shipping tag.
9. The owner of the cylinder shall be notified if any condition has occurred that might permit any foreign substance to enter a cylinder or valve, giving details and cylinder number.
10. Neither cylinders nor containers shall be placed in proximity of radiators, steam pipes, heat ducts, or other sources of heat.
11. Very cold cylinders or containers shall be handled with care to avoid injury. (Reference 9.7.2.4)

Regulators that are in need of repair or cylinders having valves that do not operate properly shall never be used. (Reference 9.7.2.6)

Personnel using cylinders and containers and other equipment covered in this chapter shall be familiar with the Pin-Index Safety System and the Diameter-Index Safety System. Both are designed to prevent utilization of the wrong gas. (Reference 9.7.4.1)

Safety relief mechanisms, noninterchangeable connectors, and other safety features shall not be removed, altered, or replaced. (Reference 9.7.4.2)
General Safety and Noise

Controlling Noise Hazards (29 CFR 1910.95) – Noise is any unwanted sound. It is created by sound waves, which are rapid vibrations in the air.

1. Noise Terms –
   + Frequency or pitch is measured in cycles per second or Hertz (Hz).
   + Amplitude or intensity is measured in decibels (dB).
   + The decibel scale is a logarithmic measure of intensity. An increase of 10 dB is 10 times as intense but is perceived as being twice as loud.
   + Perceived loudness is a subjective perception of therefore cannot be measured by an instrument.

2. Noise Exposure – Exposure to high levels of noise in the workplace is a common job hazard, even in healthcare facilities. A 1979 survey of noise levels in hospitals indicated five work areas with noise levels high enough to reduce productivity: the food service department, the laboratory, the engineering department, the business office, and the medical records section.
   + The ear changes air pressure waves into impulses that the brain interprets as sound. Hair cells in the inner ear stimulate nerves that carry the message to the brain.
   + Loud noise damages these nerves and decreases hearing acuity. Noise may also trigger changes in cardiovascular, endocrine, neurologic, and other physiologic functions.
   + Noise also hinders communication among workers.

3. Protecting Workers – healthcare facilities must protect all workers from occupational noise exposure that exceeds an 8-hour time-weighted average (TWA) of 90 decibels (dBA). The 6-hour level is 92 dB, 4-hour exposure is 95 dB, 3-hour exposure is 97 dB, and the 2-hour exposure level is 100 dB. To protect workers, the employer must:
   + Monitor noise exposure
   + Institute control measures
   + Implement a hearing conservation program (HCP) when occupational noise exposure exceeds an 8-hour TWA of 8 dBA.

4. Noise Controls – The employer must institute engineering and/or administrative controls whenever possible. If these controls fail to reduce employee noise exposure to an 8-hour TWA of 90 dBA or less, then the employer must provide and enforce the use of hearing protectors that attenuate employee exposure to at least an 8-hour TWA of 90 dBA.
   + Engineering Controls –
     - Use technology to reduce noise levels.
     - Keep machinery in good maintenance repair to minimize noise.
     - Erect total or partial barriers to confine noise.
   + Administrative Controls –
     - Limit employees’ scheduled work time in a noisy area.
     - Limit noisy operations and activities per shift.

5. Hearing Protectors – Employers must provide at no cost to the employee a selection of hearing protection appropriate for noise levels in the environment. The employer must also provide training on the selection, fitting, use and care of hearing protectors and ensure that protectors are worn. Monitoring requirements include:
   + Use only measuring instruments that meet ANSI specifications.
   + Use a sampling strategy that will pick up all continuous, intermittent, and impulsive sound levels for 80 to 130 dBA, and include all of these sound levels in the total noise measurement.
   + Permit employees or their representatives to observe monitoring.
   + Notify employees of noise exposure at or above an 8-hour TWA of 85 dBA.

6. Audiometric Testing Requirements -
   + Employmers must provide testing free of cost to employees with noise exposure equal to or above an 8-hour TWA of 85 dBA.
   + Audiometers must be calibrated to meet ANSI standards.
   + Only a licensed or certified audiologist, otolaryngologist, other physician, or a technician who is certified by the Council of Accreditation in Occupational Hearing Conservation or who has demonstrated competence in performing audiometric testing can perform such testing.
   + Baseline testing must be preceded by at least 14 hours without workplace noise exposure.
   + The use of hearing protectors during work hours may substitute for the 14-hour requirement.
   + A baseline must be established within six months of first exposure or within one year if using a mobile van to test. Hearing protection must be worn from the sixth month until testing is performed.
   + An audiogram must be obtained annually from the baseline date.

7. Audiograms -
   + Compare subsequent audiograms to the baseline audiogram to determine if there is a change in hearing threshold of 10 dB A or greater in either ear or 2000, 3000, and 4000 Hz (known as a standard threshold shift [STS]).
   + If an STS exists, the employer may retest the employee within 30 days
and use the test results as the annual audiogram.
+ Employees not already using hearing protectors must be fitted with
hearing protectors, trained in their use and care, and required to use
them.
+ Employees already using protectors must be refitted, retrained in their
use, and provided with hearing protectors that offer greater attenuation if
necessary.
+ An employee should be referred for a clinical audiological evaluation or
otological examination, as appropriate, if additional testing is necessary
or if the employer suspects that a medical pathology of the ear has been
causd or aggravated by the wearing of hearing protectors.
+ An employee should be informed of the need for an otological
examination if a medical pathology of the ear that is unrelated to the use
of hearing protection is suspected.

8. Training and Documentation –
+ A training and education program should be implemented for those
employees whose noise exposure equals or exceeds 85 dBA.
+ The training/education program should be repeated annually for
employees included in the HCP.
+ The training program should include:
The effects of noise on hearing and the purpose of hearing protectors.
Advantages, disadvantages, and attenuation of various hearing protectors and instructions on how to select, fit, use, and care for them.
Purpose of audiometric testing and an explanation of the testing procedure
+ Audiometric test records must include name and job classification of the
employee, date of the test, examiner’s name, date of the last acoustic or
exhaustive calibration of the audiometer, and the employee’s most
recent noise exposure assessment.
+ Audiometric test records should be retained for the duration of the
affected employee’s employment.
+ Noise exposure measurement records should be retained for two years.
+ Test room background noise measurements should be recorded and
maintained.
+ Access to audiometric test records and noise exposure measurement
records should be provided upon request to the employee, former
employees, the employee’s designated representative, or the Assistant
Secretary of Labor for Occupational Safety and Health.

9. Reducing Noise in the Workplace – To be successful, an occupational
HCP must be conducted using basic management concepts, beginning
with the active support of management. It is management’s responsibility
to provide and enforce the use of hearing protection, whether that
protection is wearing personal protective equipment or engineering
controls. All efforts taken to initiate the program should be documented.
All engineering control efforts should be recorded and used in determining
the feasibility of control.

10. Abatement Suggestions –
+ Mount tabletop equipment on rubber feet or pads.
+ Install sound-absorbent floor tiles.
+ Use acoustical ceiling tiles and wall hangings where possible.
+ Install mufflers where possible on generators, air compressors, etc.
+ Decrease volume of intercom speakers, televisions, and radios.
+ Keep wheels, hinges, and latches lubricated.
+ Adjust door closing mechanisms to prevent slamming.
+ Use sound-absorbent materials whenever possible.
+ Enclose noisy equipment and reduce metal-to-metal contact.
+ Limit worker exposure by implementing administrative controls.

11. Hearing Protection Evaluation – Ear protection provided for employees
is effective in substantially reducing noise exposure. Such protection may
be provided as either earplugs, earmuffs, or both. Employers are required
by the standard to evaluate the sound attenuation provided by ear
protectors for the specific environment in which the protector will be used.
Evaluation methods that must be used, according to 29 CFR 1910.95(j)(1),
are described in Appendix B of the OSHA standard.

Ultrasound Exposures – Ultrasound is the mechanical vibration of an elastic
medium that is produced in the form of alternating compressions and expansions. The vibrations may be produced by a continuous or impulse sound in the form of

+ Exposure to audible high-frequency radiation above 10 kHz can result in nausea, headaches, ringing in the ears, dizziness and fatigue.
+ Temporary hearing loss and threshold shifts are possible from high-frequency ultrasound radiation.
+ Low-frequency ultrasound radiation may produce effects if a person touches parts of the materials being processed by the ultrasound.
+ Exposure to powerful sources may damage nervous and vascular structures at the point of contact.
+ Airborne ultrasound may affect the central nervous system and organs through the ear. Exposures can be reduced by the use of enclosures and shields.
Workers should be provided with appropriate personal protective equipment for the task begin performed. Protection should also be provided for exposure to radiation above 10 kHz or when in contact with low-frequency sources.

Attachment E

Proposed ENVIRONMENTAL SAFETY CHAPTER: Fire Safety – Clinical Ignition Sources

DEFINITION(S):

Oxygen-enriched atmosphere:
99-3.3.133 Oxygen-Enriched Atmosphere. For the purpose of this standard, and only for the purpose of this standard, an atmosphere in which the concentration of oxygen exceeds 23.5 percent by volume. (HYP)
53-3.3.25 Oxygen-Enriched Atmosphere (OEA). An atmosphere in which the concentration of oxygen exceeds 21 percent by volume or its partial pressure exceeds 21.3 kPa (160 torr).

Ignition Source(s):
53-E.3.1.4 The minimum ignition energy for combustion will vary with the type of ignition source, the specific chemical nature and physical character of the combustible, and the composition and pressure of the atmosphere. Though most combustion is accompanied by a gas or vapor-phase combustion reaction, certain materials, such as metals, often burn in the liquid phase or solid phase; that is, a condensed-phase reaction. (1-5) If the reaction is to continue in the vapor phase, in the case of solids or liquids, sufficient thermal energy first needs to be supplied to convert a part of the fuel to a vapor. In all cases, for the combustion to proceed, the ignition source has to impart energy to the fuel at a faster rate than the fuel loses the energy.
The ignition sources of principal concern for oxygen-enriched atmosphere application can be categorized into the following six types:
(1) Electrical sources, such as electrostatic and break (arc) sparks
(2) Hot surfaces, such as friction sparks and heated wires
(3) Heated gases, independent of surfaces, generated by adiabatic compression or jets of hot gas, including pilot flames
(4) Exothermic chemical reactions
(5) Mechanical sources, such as frictional heating and particle impact
(6) Laser sources

Intrinsically Safe:
99-3.3.82*: As applied to equipment and wiring, equipment and wiring that are incapable of releasing sufficient electrical energy under normal or abnormal conditions to cause ignition of a specific hazardous atmospheric mixture. (HYP)

Self-Extinguishing:
99-3.3.165 Self-Extinguishing. A characteristic of a material such that, once the source of ignition is removed, the flame is quickly extinguished without the fuel or oxidizer being exhausted. (HYP)

HAZARDS:

Fire:
[Add Code and Paragraph numbers] The occurrence of a fire requires the presence of combustible or flammable materials, an atmosphere of oxygen or other oxidizing agents, and a source of ignition. Combustible materials can be unavoidably present when oxygen is being administered, but flammable liquids and gases and ignition sources are avoidable.

Oxygen-Enriched Atmosphere:
53-E.5 Effects of Fire in Oxygen-Enriched Atmospheres.
53-E.5.1 It has been noted that OEAs usually facilitate the initiation of the combustion process and, once ignition has occurred, the flame reaction proceeds with greater rapidity. Another important consideration in the analysis of the overall fire problem is that OEAs can be encountered under closed-environment (fixed-volume) conditions (e.g., in spacecraft and hyperbaric chambers). (9)

IGNITION SOURCES:

99-B.6.1.14 Sources of ignition include not only the usual ones in ordinary atmospheres, but others that become significant hazards in oxygen-enriched atmospheres (see B.6.1.7 and B.6.1.8) such as the following:
(1) Open flames
(2) Burning tobacco
(3) Electric radiant heaters
(4) The discharge of a cardiac defibrillator
(5) Arcing and excessive temperatures in electrical equipment
(6) Electrically powered oxygen apparatus and electrical equipment intended for use in an oxygen-enriched atmosphere if electrical defects are present
(7) Electrical equipment not conforming to the requirements of 8.5.2.4.1, which includes, but is not limited to, the following:
(a) Electric razors
(b) Electric bed controls
(c) Hair dryers
(d) Remote television controls and telephone handsets if introduced into an oxygen-enriched atmosphere (see 8.5.2.4.1)
(8) Rapid opening of cylinder valves, which can cause sudden increase in downstream gas pressure and temperature caused by the adiabatic heat of recompression, with consequent ignition of combustible materials in contact with the hot gas downstream, including the valve seat.
A static discharge having an energy content that can be generated under normal conditions in respiratory therapy will not constitute an ignition source as long as easily ignited substances (such as alcohols, acetone, oils, greases, or lotions) are not present.

99-C.13.1.3.3 Sources of Ignition.
C.13.1.3.3.1 Potential sources of ignition of flammable anesthetics in anesthetizing locations include all of the following:
(1) Fixed electric equipment
(2) Portable electric equipment
(3) Accumulation of static electricity
(4) Electrosurgical equipment
(5) Open flames and heated objects above the ignition temperature of the flammable gases in use.

Other potential sources of ignition are percussion sparks, ignition of oxidizing and flammable gases from accidental mixing under pressure (9.3.9), and ignition from improper handling of oxygen cylinders (9.4.3.3, 9.4.3.5, and 9.7.2).

EDUCATION/TRAINING:

53-D.5.2.5 In-Service Training: The health care facility administration should institute an obligatory in-service training program for the surgical staff and others involved in the use of high-frequency energy sources. With the current rapid changes in medical device technology, many techniques that were appropriate a short time in the past are no longer so. There is a great potential for patient injury and fire ignition if these high-powered energy devices are improperly used. Education and retraining are essential to avoid these hazards.

REFERENCES:


Attachment F

Proposed ENVIRONMENTAL SAFETY CHAPTER: HAZARDOUS MATERIALS & WASTE SECTION

I. APPLICABILITY

This chapter establishes criteria to minimize the hazards of fire and explosions as well as address non-fire safety issues regarding hazardous materials and waste in health care occupancies.

NFPA 45: Standard on Fire Protection for Laboratories Using Chemicals, is the basic NFPA standard for the storage, handling, and use of chemicals in laboratories.

NFPA 500, Standard for Storage, Handling, and use of Ethylene Oxide for Sterilization and Fumigation*, is the basic NFPA standard for Ethylene Oxide that covers the storage, handling, and use of ethylene oxide in all facilities. However, this chapter has additional requirements relating to the use of ethylene oxide (and other hazardous materials) in health care facilities

ANNEX MATERIAL:

* Please note that this standard would not apply to most hospitals because the standard does not address 1) non-flammable mixtures of ethylene oxide with other chemicals and 2) ethylene oxide in chambers 10 ft3 or less in volume, or for containers holding 7.05 oz of ethylene oxide or less.

Those hospitals using the larger ethylene oxide sterilizers typically use a non-flammable mixture. Those hospitals using the 100% EtO typically use the smaller table top sized sterilizers with chambers less than 10 ft3 and cartridges less than 7.5 ounces.

Thus, for most hospitals there are no standards governing EtO use other than what is in the OSHA standard and in fire codes dealing with storage of compressed gas cylinders.

II. Hazardous Materials

A. Communication of Hazards

(NFPA 45: 10.3.1) Content identification, including precautionary information, shall be provided directly on all original and subsequent containers of hazardous chemicals, in accordance with OSHA requirements in 29 CFR 1910.1200, Hazard Communication Plan.

B. Handling

(NFPA 45: 7.1) When a chemical is ordered, steps shall be taken to determine its hazards and to transmit that information to those who will receive, store, use, or dispose of the chemical. Restrictions imposed by governmental regulations shall be followed.

(NFPA 45: 7.2.2.1) Receiving, transporting, unpacking, and dispensing of chemicals and other hazardous materials shall be carried out by trained personnel in such locations and in such a manner as to minimize hazards from flammable, reactive, or toxic materials.

(NFPA 45: 7.2.2.4) Before a chemical material is used, the user shall determine that the information and facilities are available for safe disposal of hazardous materials and waste products that may be generated.

C. Storage

Storage of incompatible chemicals

(NFPA 45: 7.2.3.4) Incompatible materials shall be segregated to prevent accidental contact with one another.

All employees handling hazardous materials and wastes shall be trained in safe handling and storage practices. The training materials shall include information on identifying incompatible chemicals. (See EPA Chemical Compatibility Chart in annex).

ANNEX MATERIAL:

- Used batteries are a fire-hazard due to their remaining electrical current and an explosion hazard due to the reactivity of their components such as Lithium. Batteries should be stored inside in a cool, dry place away from flammable material.

* Incompatible chemicals can be found throughout a typical health care institution such as in laundries, boiler rooms, maintenance shops, housekeeping storage areas, waste holding, and laboratories.

Hazardous Waste Storage (follow Life Safety & EPA regs)

D. Use

Health care organizations shall comply with applicable OSHA regulations to monitor specific chemical exposures.

Health care organizations shall comply with NIOSH recommendations to monitor waste anesthetic gas exposures

ANNEX MATERIAL:

* Ventilation (general & local) See ASHRAE 170P Ventilation of Health Care Facilities

E. Disposal (11.7.5)

Disposal

(NFPA 99: 11.7.5) Disposal of hazardous materials shall be accomplished off the premises by a disposal specialist or at a safe location away from the health care facility by competent personnel using procedures established in concurrence with the authority having jurisdiction.

Where permitted by the authority having jurisdiction, appropriate hazardous materials may be disposed of on site by competent personnel using approved methods.

Solvent Recycling

Solvent recycling operations in health care facilities shall be conducted in a well ventilated area that is appropriately protected as a hazardous area per NFPA 101 Life Safety Code. Spill clean up procedures shall be in place and adequate spill clean up materials and non-sparking tools shall be available.

III Emergency Procedures

(NFPA 11: 2.1.3.3) Emergency procedures shall be established for controlling hazardous material spills.
A fire safety risk assessment shall be made for all hazardous material and waste within a health-care facility. This assessment shall include provisions for routine monitoring of areas using or storing hazardous materials/wastes to evaluate changes in conditions/use that may create increased risk of fire or explosion. Appropriate emergency response plans shall be developed to address identified hazards.

Spill prevention and cleanup activities for large spills that cannot be safely cleaned up by the trained staff of the health care facility shall be done in accordance with OSHA 29 CFR 1910.120 “Hazardous Waste Operations and Emergency Response.”

A Spill Prevention, Control, and Countermeasure plan shall be developed in accordance with EPA 40 CFR 112 Spill Prevention, Control, and Countermeasure (SPCC) rule which requires operating procedures to prevent spills, control measures to prevent oil from entering navigable waters, countermeasures to contain/cleanup spill.

Above ground storage tanks on site shall comply with applicable local, state, and federal regulations and shall be a minimum of 5 feet from the nearest building or the nearest side of any public way.

IV. Ethylene Oxide (EtO)

Ethylene Oxide sterilizers and related equipment such as EtO aerators, EtO alarms, and any EtO local exhaust equipment shall be connected to emergency power (i.e. the essential electrical system).

ANNEX MATERIAL:

- This would allow the EtO sterilizer to finish its cycle and allow the EtO aerator to continue to vent the offgassing EtO. Note: Those hospitals that wish to continue to admit patients and operate during a power outage should put their entire central sterile processing department on emergency power.

Local exhaust ventilation shall be provided near EtO tanks in sterilizer recess room or wherever the EtO tanks are located.

EtO supply and exhaust piping shall be identified and provided with appropriate warning labels. EtO piping that is located within a room already identified as a regulated area for EtO need not be labeled.

ANNEX MATERIAL:

- It is particularly important, for example, that EtO exhaust piping leading from the sterilizer recess room to an abatement device and on to an external exhaust be identified to alert any maintenance or contract worker of this hazard.

Cartridges containing flammable mixtures of EtO such as the 100% EtO cartridges (3.5 to 6 ounces) in quantities exceeding 40 ounces shall not be stored in the work area outside of a flammable liquids storage cabinet.

Flexible piping shall not be used for EtO exhaust except within an established EtO regulated area that is equipped with exhaust ventilation.

(NFPA 560: 5.1.1) Storage areas of ethylene oxide shall be secured against unauthorized entry.

(NFPA 560: 8.3) Area Monitoring for Ethylene Oxide

Ethylene oxide sterilizer areas shall be monitored continuously for ethylene oxide concentrations. In health care facilities the continuous ethylene oxide alarm monitor shall have, at a minimum, a high alarm in the vicinity of the sterilizer/aerator set to alarm above 20 ppm.

ANNEX MATERIAL:

The requirements for EtO monitoring in NFPA 560 appropriately deal with detecting flammable levels of EtO. These monitors are set to detect only very high levels of EtO and are not designed to detect EtO at very low levels where an alarm would help protect workers from harmful EtO exposures.

V. Misc Issue Relating to Equipment:

Medical Waste Processing Equipment (Autoclaves, Microwaves, etc)

Written policies shall be in place for the safe operation of any on-site medical waste processing equipment. These shall address the hazards of fire and explosion and shall include procedures for ensuring that hazardous materials which may lead to fire and explosions within the unit are properly segregated from the waste and not processed.

Attachment G

Proposed ENVIRONMENTAL SAFETY CHAPTER: Imaging Safety

ASHE Workgroup proposal: Each of the pieces of equipment included in the definitions section shall be written based on associated hazards for each occupancy and each category of personnel. Additionally, enforcement of these duties will include the “who, what, where, and when.” For example, it is the responsibility of the Safety Officer or equivalent to conduct a proactive hazard vulnerability assessment (HVA), for each of the pieces of equipment based on their location within the organization (occupancy) with regard to personnel present in that environment. The HVA shall be inclusive of fire prevention, emergency preparedness, and orientation and training. The proactive HVA will take the organization’s overall HVA to a more defined internal hazard approach.

PROPOSED SECTION FORMAT

Definitions:

- General Imaging: Ultrasound Scan and Diagnostic Radiology
- Computed Tomography (CT) Scanning
- Positron Emission Tomography (PET)
- Magnetic Resonance Imaging (MRI)
- Linear Accelerator

Hazards:

1. Electrical
   a. High Voltage
   b. Electrostatic

c. Ground fault
d. Shock
e. Emergency power/UPS

2. Gases
   a. Piped gases
      i. Oxygen
      ii. Vacuum
      iii. Suction
   b. Cylinders

3. Anesthetizing

4. Radiation

5. Ergonomics – patient lifting

6. Fire
7. Radio Frequency Interference (RFI)
8. Floor Conductivity
9. Precautionary signs
10. Access control

Categories:
I. Facility/Environment

   1. Occupancy
      a. Business
      b. Ambulatory
      c. Healthcare

   2. Equipment
      a. General Imaging
      b. CT Scanning
      c. PET
      d. MRI
      e. Linear Accelerator

   3. Personnel
      a. Patient
      b. Healthcare Worker
      c. Emergency Responder

   4. Enforcement
      a. Safety Officer or equivalent responsibilities
      b. Hazard Vulnerability Assessment (HVA)
      c. Fire Prevention
      d. Emergency Preparedness
      e. Orientation and Training

References

Attachment H
Proposed ENVIRONMENTAL SAFETY CHAPTER: Infection Control- Regulated Medical Waste and Alcohol-Based Sanitizers and Skin Prep Products

I. APPLICABILITY
This chapter addresses various aspects of regulated medical waste and other infectious agents in health care facilities in order to minimize the hazards of fire and explosions as well as minimize exposure to infectious substances or associated safety and health hazards.

II. Background
This chapter addresses two key infection control issues - regulated medical waste (RMW) and the use of alcohol-based products used in healthcare occupancies including a) alcohol-based hand sanitizers and b) alcohol-based patient skin preparations

III. Regulated Medical Waste (RMW)
It is recognized that currently there is no national policy or single standard defining RMW. RMW is defined and regulated by each state. Federal regulatory agencies that enforce different aspects of managing or disposing of RMW include the U.S. Department of Transportation (DOT), the Environmental Protection Agency (EPA) Occupational Safety and Health Administration (OSHA) and the U.S. Postal system.

See background

A. Medical Waste Policies and Procedures
A health care facility shall manage regulated medical waste (RMW) in a way that prevents the spread of disease and complies with all applicable federal, state, and local regulations.
All health care facilities that generate RMW shall develop a regulated medical waste management plan.
Hazardous chemicals or pharmaceuticals (e.g., EPA-listed or exhibiting hazard characteristic) should not be combined with regulated medical waste.

B. Packaging and Labelling
All regulated medical wastes shall be packaged, contained and located in a manner that prevents and protects the waste from release at the facility or at any time before ultimate disposal.
All regulated medical waste packages or containers shall be clearly identifiable by means of unique color-coding or standard label/biohazard symbol. Labelling must also be in accordance with the OSHA Blood Borne Pathogen Standard where applicable. Sharps containers shall not be overfilled. For the purposes of this standard “overfilled” is taken to mean over 90% of the volume of the container or above a full line indicated on the sharps container, whichever is less.

C. Storage

Regulated medical waste stored in a generating facility shall be stored in such manner that putrefaction will not occur and infectious agents will not come in contact with the air or individuals.

Regulated medical waste shall be stored in a well ventilated area that is maintained under negative air pressure with respect to adjacent areas. Exception: Temporary holding areas where RMW is held for less than 24 hours.

Regulated medical waste shall not be stored outdoors or in any unsecured area but shall be stored in a secured area to prevent access to the waste by unauthorized individuals who are not responsible for disposal.

Regulated medical waste shall not be placed in trash chutes or compacted at a trash disposal site.

D. Handling

Regulated medical waste shall be handled in such a manner to minimize the aerosolization of airborne infectious agents.

Medical waste other than sharps shall be contained in bags other than body pouches or other containers that are impervious to moisture and have strength sufficient to resist ripping, tearing, breaking, or bursting under normal conditions of usage or handling. The bags or containers shall be secured so as to prevent leakage during storage, handling, or transport.

E. Disposal

A health care facility shall dispose of RMW in a way that prevents the spread of disease and complies with all applicable federal, state, and local regulations.

Disposal of RMW shall be accomplished off the premises at a location away from the health care facility by competent personnel using procedures established in concurrence with the authority having jurisdiction.

Where permitted by the authority having jurisdiction, RMW may be disposed of on site by competent personnel using approved methods.

- Medical Waste Processing Equipment (Autoclaves, Microwaves, Incinerators, etc)

Written policies shall be in place for the safe operation of any on-site medical waste processing equipment. These shall address the hazards of fire and explosion and shall include procedures for ensuring that hazardous materials which may lead to fire and explosions within the unit are properly segregated from the waste and not processed. See Background

IV. Alcohol-Based Products – Health Care

A. Alcohol Based Hand Rubs

Scope and Authority


- The Centers for Medicare and Medicaid (CMS) published a final rule with an effective date of 10 23 06 adopting the TIA for NFPA 101-2000, Life Safety Code for the following: Hospitals, Ambulatory Surgical Centers, Nursing Homes, Religious Non-Medical Health Care Institutions, Programs of All-Inclusive Care for the Elderly (PACE) Facilities, Critical Access Hospitals, Intermediate Care Facilities for the Mentally Retarded – Adoption of a New Fire Safety Amendment for the Use of Alcohol Based Hand Rubs (ABHRs).

- The TIA is silent on application to either gels or foam formulations and the following conditions apply to either ABHR gels or foams.

Conditions

The amendment permitting ABHR to be used in exit access corridors shall meet certain requirements:

1. The use of ABHRs shall conform to state and local laws.
2. The dispensers shall be installed in such to minimize leaks and/or spills.
3. The dispenser(s) shall be installed to adequately prevent access by vulnerable populations.
4. Installation of dispensers in corridors shall meet the following conditions required in Chapter 18 for New health care occupancies and Chapter 19, Existing healthcare occupancies, listed here for:

3.2.6 Alcohol-Based Hand-Rub Dispensers.

Alcohol-based hand-rub dispensers shall be protected in accordance with 8.7.3, unless all of the following conditions are met:

Installation

- Where dispensers are installed in a corridor, the corridor width shall have a minimum width of 6 feet (72 in.)
- The dispensers shall have a minimum horizontal spacing of 4 feet (48 in.) from each other.
- The maximum individual dispenser fluid capacity shall be 1.2 liters (.32 gal) for dispensers in rooms, corridors, and areas open to corridors, and 2.0 liters (.53 gal) for dispensers in suites of rooms.
- The dispensers shall not be installed over or directly adjacent to an ignition source.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

Storage

- Not more than an aggregate of 37.8 liters (10 gal) of alcohol-based hand-rub solution shall be in use in a single smoke compartment outside of a storage cabinet.
- Usage and Dispenser location - Adjacency
- Adjacent and directly over an ignition source
- The dispenser shall not be directly over the outlet so that gel will not drip into an outlet (or on plugs inserted into the outlet) - as a small spark may be created when unplugging a piece of equipment which is in the on mode).
- Adjacent and next to an ignition source.
- The dispense shall be installed at least 6 inches from the center of the dispenser to an ignition source.

B. Alcohol-based Surgical Patient Skin Preparations

Scope and Authority
National Fire Protection Association (NFPA) approved a proposed Tentative Interim Amendment (TIA) to NFPA 99 - Standard for Health Care Facilities - 2005 edition in July 2005 effective August 18, 2005, and is subject to the review and approval by the full NFPA code development process for the 2009 edition of the standard.

**Conditions**

Use of germicides and antiseptics in the surgical suite shall be used as outlined:

### 13.4.1.2.2 Germicides and Antiseptics

13.4.1.2.2.1 Medicaments, including those dispersed as aerosols, shall be permitted to be used in anesthetizing locations for germicidal and antiseptic purposes, for affixing plastic surgical drape materials, for preparation of wound dressing, or for other purposes.

13.4.1.2.2.2 Flammable liquid germicides or antiseptics used in anesthetizing locations, whenever the use of electro-surgery, cautery or a laser is contemplated, shall be packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, and other similar applicators.

13.4.1.2.2.3 Whenever the application of flammable liquid germicides or antiseptics is employed in surgeries where the use of electro-surgery, cautery or a laser is contemplated, time shall be allowed to elapse between application of the germicide or antiseptic and:

a) The application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining, and

b) The use of electro-surgery, cautery or a laser to ensure the solution is completely dry and to permit thorough evaporation and dissipation of any flammable vehicle remaining.

13.4.1.2.2.4 Any solution-soaked materials shall be removed from the operating room prior to draping or use of electro-surgery, cautery or a laser.

13.4.1.2.2.5 Pooling of flammable liquid germicides or antiseptics shall be avoided.

13.4.1.2.2.6 A preoperative “time out” period shall be conducted prior to the initiation of any surgical procedure using flammable liquid germicides or antiseptics to verify that a flammable germicide or antiseptic:

a) application site is dry prior to draping, and use of electro-surgery, cautery or a laser, and

b) that pooling of solution has not occurred, or has been corrected, and

c) any solution soaked materials have been removed from the operating room prior to draping and use of electro-surgery, cautery or a laser.

13.4.1.2.2.7 Whenever flammable aerosols or antiseptics are employed, sufficient time shall be allowed to elapse between deposition and application of drapes to permit complete evaporation and dissipation of any flammable vehicle remaining.

13.4.1.2.2.8 Health care organizations shall establish policies and procedures outlining safety precautions related to the use of flammable liquid or aerosol germicides or antiseptics used in anesthetizing locations, as required in Section 13.4.1.2.10 whenever the use of electro-surgery, cautery or a laser is contemplated.

**APPENDIX MATERIAL — Background Regulated Medical Waste**

Congress enacted the Medical Waste Tracking Act (MWTA) in November 1988, which added medical waste tracking provisions to RCRA Subtitle J. The Act directed EPA to establish a two-year demonstration program for the tracking of medical waste, which began in 1989 and ended in 1992. Since the MWTA expired, no federal tracking regulations are in effect. States have developed programs similar to the federal model. While medical waste is not regulated under the current federal RCRA regulations, there are federal requirements for medical waste under the Clean Air Act (CAA) for medical waste incinerators and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for pesticides and chemicals used in medical waste treatment technologies.

**Federal Regulatory Agencies with Responsibilities for RMW**

**EPA**

Medical waste is generally defined under state regulations. Medical waste is often described as any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, Past MWTA included:

- Cultures and stocks of infectious agents
- Human pathological wastes (e.g., tissues, body parts)
- Human blood and blood products
- Used sharps (e.g., hypodermic needles and syringes used in animal or human patient care)
- Certain animal wastes
- Certain isolation wastes (e.g., wastes from patients with highly communicable diseases)
- Unused sharps (e.g., suture needles, scalpels, hypodermic needles).

These have been modified state by state and focus more on the burden of bloodborne pathogens, or “infectious substances and typically do not include “certain isolation wastes” or “unused (clean) sharps.”

**STATE DEFINITIONS — Example: A typical state definition may define medical waste to mean any of the following:**

- Cultures and stocks of infectious agents and associated biologicals, [including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture dishes, and related devices]
- Liquid human and animal waste including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids
- Pathological waste [human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery or autopsy or other medical procedures and not fixed in formaldehyde]
- Sharps- Sharp may be defined as any object that is able to cut or penetrate the skin or packaging material and may include but is not limited to a needle, syringe, scalpel, lancets, broken vaccine vial, culture slide or dish, capillary tube and intravenous tubing with a needle attached.
- In at least one state, “syringe,” is interpreted by Rules as syringes with an attached needle and those parts of a syringe, with or without an attached needle, that are contaminated with a potentially infectious agent. Needles shall only be removed from a syringe in accordance with established procedures (i.e., OSHA)
- Contaminated wastes from animals used in research that have been exposed to agents infectious to humans. This shall include but not be limited to carcasses body parts, body fluids, blood, feces or bedding.

**EPA now references other agencies, state definitions and regulations for management and disposal of RMW related to health care occupancies including the following federal agencies:**

**A. DEPARTMENT OF TRANSPORTATION (DOT)**

DOT addresses infectious substances and RMW that cross state lines and affect healthcare occupancies including training of handlers of RMW

**DOT CFR 49:**

1. §173.196 Infectious substances

   Compliance with DOT 2006 Final Rule for Transport of Infectious Substances includes sharps containers that are:
   a. Leakproof in all orientations for contents and residual fluids during transport
   b. Securely closed to prevent closure loosening
   c. Puncture resistant

99/L411/A2011/ROP/Rec 17
2. §173.197 Regulated medical waste
   a. Sharps. Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in § 178.601 of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria

B. Occupational Safety & Health Administration (OSHA)
   Bloodborne pathogens - 1910.1030
   DEFINITION

   Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials

   Regulated Waste (d) (4) (iii) (A) Contaminated Sharps Discarding and Containerment.
   Contaminated sharps shall be discarded immediately or as soon as feasible in containers. Sharps containers shall be:
   - Closable
   - Puncture resistant
   - Leakproof on sides and bottom
   - Labeled or color-coded (and cabinetry if present) according to paragraph (g) (1) (i) of the standard.
   - When moving containers of contaminated sharps from the area of use the containers shall be
   - containers shall be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping
   - containers shall show no sign of leakage of fluids during handling, storage, transport, or shipping
   - if the container cannot be sealed to prevent leakage it must be placed in a leakproof secondary container constructed to contain all contents during handling, storage, transport or shipping

C. U.S. Postal system
   10.17.1 General
   Division 6.2 materials include infectious substances, biological products, regulated medical waste, sharps medical waste, used health care products, and forensic materials.
   DEFINITION
   - Regulated medical waste, for USPS purposes, means a soft waste material (other than a sharp) derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Soft medical waste includes items such as used rubber gloves, swabs, gauze, tongue depressors, and other similar material.
   - Sharps medical waste, for USPS purposes, means a medical waste object that is capable of cutting or penetrating skin or packaging material and that is contaminated with a pathogen or may become contaminated with a pathogen derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.
Prohibited uses of medical gases include fueling torches, blowing down or drying any equipment such as lab equipment, endoscopy or other scopes, or any other purposes. Also prohibited is using the oxygen or medical air to raise, lower, or otherwise operate booms or other devices in operating rooms (ORs) or other areas. **Permitted uses** would be for the operation of USFDA registered medical devices such as ozone sterilizers which require the use of medical grade oxygen for proper operation and operate at a pressure lower than the oxygen supply piping network.

**Substantiation:** When the Technical Committee adopted the requirements in section 5.1.3.4.2 they were looking to protect the central supply system from hazards such as contamination and pressure fluctuation. The example provided in the annex for fueling torches applies to the oxygen central supply system. In this application the concern was the contamination of the central supply system from a back flow of the fuel gas which is being blended with the oxygen. There was also concern for the pressure fluctuation which can occur from the flow rate of oxygen required in certain torch applications. When the 125L Ozone Sterilizer is supplied with medical grade oxygen from the central supply system these hazards do not exist. The Ozone Sterilizer does not use any fuel or other gases in its operation and the flow rate of oxygen required is similar to some patient applications.

**Committee Meeting Action:** Reject

**Committee Statement:** See the Committee Action on Proposal 99-159 (Log #116a).