What's In the Codes and Why

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INTRODUCTION

This lecture addresses the set of codes and standards that primarily affect the acquisition, operation and maintenance of clinical hyperbaric facilities. The focus is primarily on issues related to the operation and care of the hyperbaric chamber and its related systems. No attempt is made to address issues related to staffing, personnel competency and related topics. Also addressed are issues currently under active discussion within the codes and standards committees or issues that are typically contentious topics.

OBJECTIVES

Upon completion of this presentation each participant should be able to discuss which codes and standards apply to acquisition, operation and maintenance of clinical hyperbaric facilities and the general procedures by which those codes and standards are developed, interpreted and enforced.

LECTURE OUTLINE

I. Sect 1: Applicable Rules, PVHO Topics

A. Applicable Rules

1. Level 1 (The "Major Technical Players")

a) NFPA 99-2012 Health Care Facilities, Chapter 14 "Hyperbaric Facilities" (Ch 19 or 20 in earlier editions)

(1) Fire safety

(2) Electrical safety

(3) Selected gas handling issues (air quality, gas storage)

(4) Facility administration (operation, maintenance, etc.)

(5) Oxygen & air service req'ts (what rules apply & where)

b) TODAY'S SURPRISE: Regarding Initial Construction,

NFPA 99 Has "No Standing" in States with Building Codes Derived From the International Building Code (IBC). Includes MI, CA, VA, PA, NJ & several others (See Att. A)

(1) BC references Int'l Plumbing Code (IPC)

(2) IPC requires med gas plumbing iaw NFPA 99 Ch 5 (generally applied only to the site piping-but enforcement can be draconian)

(3) No reference anywhere to NFPA hyperbaric rules EXCEPT an obscure reference in NFPA 101, Life Safety Code, which is also not universally adopted.

(4) Can be permitted to use NFPA 99, Ch 14 – But open for expensive conflicts regarding site plumbing work & sprinkler req'ts

(5) This situation needs "fixing" (but not likely any time soon)!!!

c) ASME PVHO-1-2007: Safety Standard for PVHOs

(1) Pressure vessel & piping structural integrity

(2) Operational safety aspects of system design (depth gauge plumbing, gas switching, etc.)

(3) Requires non-air relief valve exhausts to be piped outdoors (This can be an issue!!)

d) ASME PVHO-2-2003: In-Service PVHO Acrylic Windows Guidelines

(1) Permissible flaw sizes & when repairable

(2) Window service life

(3) Published February 2004 ($50, www.ASME.org)

(4) New edition due out in 2012 (sometime)

2. Level 2 (Typically Level 1 Rule Sets Plus Specific Additions)

a) FDA Medical Device Rules & Good Manufacturing Practice Rules

b) Accreditation Organizations: JCAHO, UHMS, IHMA

c) Nat'l Board of Diving and Hyperbaric Medical Technology

d) OSHA & USCG

e) Individual state pressure vessel laws & regulations (awareness is abysmal, compliance is often poor)

(1) Does your facility comply?

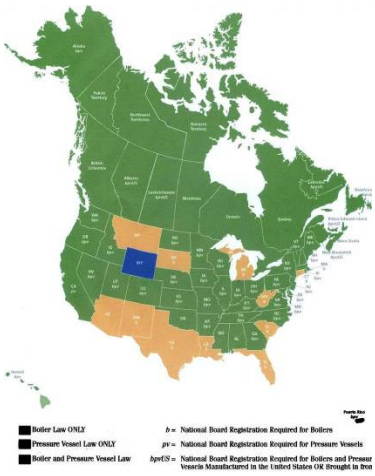
(2) Many states now required National Board registration as well as ASME Code/PVHO stamping. State pressure vessel inspectors have "real teeth" and they bite!!!!!!!

3. Level 3 (Typically Apply Only to Limited Areas or Specific Devices)

a) CGA, AWWA, Uniform Fire Code, Uniform Building Code,

b) Local Jurisdictional Rules (jungle rules)

4. Regulatory – National Board (BPV)



a) 11 states - Boiler Law only

b) 1 state - Pressure Vessel Law only

c) All other states - Boiler and Pressure Vessel Laws

d) PVHO also req'd by: AR, CA, DL, GA, HI, MN, NC, OR, TN, WA, WI and cities of Denver, WDC & Seattle.

e) What does that mean?

(1) The National Board lists the stamping requirements for each state (the stamp for hyperbaric chambers is the ASME "U" stamp).

(2) Cross reference to ASME (and thereby PVHO) for Pressure Vessel Codes.

(3) Hyperbaric chambers in states with Pressure Vessel Laws have to be registered, certified, and inspected annually….But….very few are….

5. Nat'l Board Stamping-What Does it Mean?
    a) A Nat'l Board Stamp on the vessel data plate means that you can call the National Board and for about $35 have a copy of the ASME Form U-1 or U-1a (sort of a birth certificate for the vessel) on your fax machine in about 2 hours.
    b) The From U-1 (or U-1a) lists the major vessel dimensions, major materials, weld inspection criteria, working pressure, test pressure, etc. E.g. Most of the info one would need to know if it became necessary to make a repair of alteration to the vessel.
    c) In many states, lack of a nat'l board stamp may require removal of the vessel from that state. State pressure vessel inspectors have "real teeth" and they bite!!!!!!!
    d) Nat'l Board cannot get you PVHO chamber or window forms. Get them from chamber mfr.
6. Get more info – National Board
    a) To access a summary of the pressure vessels laws in your state (and everywhere else in North America) go to: www.NationalBoard.org
    b) Click on the "Members Only" tab and go through the sign up process
    c) Once registered (free, usually takes about 24 hours), under the "Members Only" section go to a sub-section called "Resources"
    d) Under "Resources" click on "Nat'l Board Synopsis" and view the document. Then find the pages for your state.
    e) www.NationalBoard.org, "Jurisdictions", "View our Members", (your state) will get you the info for the state inspectors office without having to register.

B. Types of Chambers
1. Diving Chambers
    a) Occupants are being paid, usually extra, to expose themselves to hyperbaric conditions. Creature comfort is important, but not a driving force.
    b) Occupants are required to have prior training in hyperbaric physiology & operations.
    c) Occupants are normally physically fit, even if being treated for DCS.
    d) Attendants are normally young and physically fit.
    e) Infectious disease hazards are modest and easily managed.
    f) Primary rules: USCG, OSHA, PVHO, Marine Classification Societies
2. Medical Chambers
    a) Occupants are paying to be exposed to hyperbaric conditions. Patient comfort is important for reasons of economics, treatment effectiveness and safety.
    b) General public is involved. Patient knowledge of hyperbaric technology is generally poor to non‐existent.
    c) Occupants must be assumed to be physically unfit, possibly obese & helpless.
    d) Attendants may be any age, male or female and cannot be assumed to be physically strong.

e) Infectious disease hazards are plentiful and constant vigilance is necessary. Chamber design must address ID issues.

f) Primary rules: NFPA, FDA, PVHO, JCAHO, State PV Regs

g) Patient egress in event of operator incapacity must be considered. So must be patient evacuation in event of fire.

h) A MEDICAL CHAMBER IS NOT A DIVING CHAMBER THAT JUST HAPPENED TO COME INDOORS

3. Inflatable Chambers

a) All inflatable chambers used for medical purposes are subject to FDA oversight as medical devices

b) SOS Hyperlite is a 3 ATA rated chamber built under PVHO-1 Rules, Case 12 and has an FDA 510(k) clearance for unrestricted use.

c) Of the "zippered bag type" chambers, most are now built under an FDA clearance of some sort.

d) Some of the clearances are for use treating altitude sickness at pressures up to 3 psig with air pressurization only with no accompanying clearance to use oxygen breathing devices in the chamber. Some clearances do include the use of oxygen as a breathing gas via mask/hood.

e) FDA is not effectively enforcing the rules. Consequently, this is a "buyer-beware" market.

f) Types of Chambers: Inflatable Chambers

g) Some inflatables are un-cleared knock-offs. If a chamber does not carry a tag indicating the manufacturer and serial number, the chamber is likely a knock-off, and probably illegal.

h) Most are not yet built under PVHO-1 rules. PVHO Case 15 became available in April 2010 and allows a specific zippered chamber design to be certified under PVHO rules for pressures up to 2 ATA.

i) Most inflatable chambers are NOT required to conform to state pressure vessels laws due to "less than 15 psig" exemption from inspection in most states (not so in WI). PVHO-1 rules are applicable when the vessel is pressurizable past 2 psig IF so adopted by an AHJ.

C. Why Do We Have All These Rules & Regs

1. Codes & Standards: General Considerations
2. Codes & Standards: The Major Players
3. For each code/standard are summary of:

a) Type (voluntary consensus standard, Federal reg, etc.)

b) Scope of application (when does it apply)

c) Primary thrust (technical/operational areas covered)

d) Rule making procedures (by whom and how)

e) Enforcement (by whom and how)

f) Current issues

4. How to Access the FDA's Web Site for a list of hyperbaric chambers with 510(k) Pre-Market Clearances (pg 12)
5. Phone/fax/website info for sources of the major codes (pg 12)
6. PVHO Topics Applicable to Existing Facilities
    a) Service life of windows. "Design Life" as used in PVHO-1 does NOT equate to service life. The service life can be 1 day or much longer than the design life depending on how the window is used. See PVHO-2 for service life limitations.
    b) Depth Gauges: On a dedicated line
    c) Relief Valve Exhausts: Non-air exhausts req'd to be piped outdoors. Must consider possible over-pressurization of the space housing the cbr (Historically compliance = abysmal)
    d) Gas Switching: "Positive" means of ensuring the correct gas is delivered and no possibility of back-flowing one feed gas into the other.
    e) Minimum pressure differential for PVHO rules to apply: 2 psid
7. New Standard: ANSI/ASME PVHO-2
    a) In-service Guidelines for PVHO Acrylic Windows
    b) Type: Industry Consensus Standard (ANSI rules)
    c) Publication Date: February 2004
    d) Current Scope:
        (1) "….criteria and guidelines for the in-service inspection, care, repair or replacement, testing, and re-certification of PVHO acrylic windows in Pressure Vessels for Human Occupancy."
        (2) Applies only to windows built initially to PVHO-1 rules.
    e) Future Scope:
        (1) In process of being expanded to include in-service guidelines for maintaining the entire PVHO system. Major changes in the next edition (due 2012 sometime)
    f) Primary Thrusts:
        (1) Frequency and methods of inspection for in-service PVHO windows
        (2) Requirements for PVHO window inspectors (still working on how to train & certify the inspectors)
        (3) Criteria for evaluating windows flaws that may occur in service such as cracks, gouges, scratches, crazing and chips ("bottom line" = typical flaw has to be really "ugly" in a visual sense before it is structurally significant)
        (4) Sets limits on how long various types of windows can be left in service beyond their PVHO "design life" on the basis of visual inspections alone (more w/testing):
            (a) 10 years or 5,000 cycles for most windows in protected environments
            (b) 10 years and 10,000 cycles for a cylindrical monoplace windows (total life = 20 yrs, 20,000 cycles) in protected invironments
            (c) All windows: complete seat/seal inspection at 10 years

(d) No extension for windows not in protected environments without additional life tests of similar windows.

(5) Provides mechanisms for extending the service life of most PVHO window forms based on extended life testing

D. What Rules Apply Where?

1. Monoplace Facilities, Oxygen Ventilation

a) Facility and chamber design:

(1) Bldg Codes and/or NFPA 99, Ch 14;

(2) PVHO-1 & -2

(3) Texas Dept of Health Rules

(4) UHMS Hyperbaric Facility Design Guidelines

b) Oxygen supply: NFPA 99, Ch 5 and/or 14. Major clarifications in 2012 Edition of NFPA 99.

c) Gas storage within the facility: NFPA 99, Ch 5; NFPA 55, local Bldg Code

d) Electrical supply: NFPA 99, Ch 4

e) Diagrams in Attachment A & In Hyperbaric Chamber Safety.

2. Monoplace Facilities, Air Ventilation

a) As above plus air compressors may fall under Ch 19/20 or Ch 5 (2005 and earlier editions). Some confusion re Ch 14 or Ch 5 in 2nd Ed.

3. Multiplace Facilities

a) As above plus AWWA rules for water supply

b) Add'l precautions req'd for piped connections to hospital vacuum or sanitary drain systems and to room overpressure.

c) Diagrams in Attachment A & In Hyperbaric Chamber Safety.

II. Section 2: NFPA 99, Facility & Non-Electrical Requirements (Add'l Information in Attachment B.)

A. Main NFPA 99 Chapters (2002 & 2005 Ed.)

General Chapters 1-3

1. Introduction

2. Referenced Publications

3. Definitions

Requirements Chapters 4-11

4. Electrical Systems

Types 1, 2, & 3

5. Gas and Vacuum Systems.

Levels 1, 2, 3, 4, & 5

6. Environmental Systems
7. Materials
8. Electrical Equipment
9. Gas Systems
10. Manufacturing Req'ts
11. Laboratories
12. Health Care Emergency Mgmt

Application Chapters 13-21

13. Hospital Requirements
14. Other Health Care Facilities
15. Reserved (not used)
16. Reserved (not used)
17. Nursing Home Req'ts
18. Limited Care Facility Req'ts
19. Electrical & Gas Equipment for Home Health Care
20. Hyperbaric Facilities (Ch 14 in 2012 edition)
21. Freestanding Birthing Centers

Appendices

A. Explanatory Material (Very specific information & recommendations keyed to individual sections)

B. Nature of Hazards

C. Additional Explanatory Notes to Chapters 1-20 (More general information. Keyed to individual chapters only). Includes suggested procedures for use in the event of fire inside or outside a chamber.

D, E & F (of limited interest to HBO)

B. The Asterisk (*) Mystery

1. Many paragraph numbers in NFPA 99, Ch 20 are followed by an asterisk such as 20-2.2.3*.
2. What does the asterisk mean? Is it of any interest?
3. (*) = more information (often very valuable) in Appendix A.
4. Train yourself to watch for the asterisks. They can save you much time.

C. NFPA 99 Chapter 14

1. Application (14.1.1)
   a) New construction

b) New equipment added to existing facilities

c) Altered, remodeled or modernized portions of existing facilities

2. What about existing equipment?

a) Can continue to use so long as a) it is maintained in accordance with initial code of construction and b) continued use does not constitute an immediate hazard to life (rare).

b) Example, Can you move a pre-PVHO chamber into a PVHO state? Answer: Maybe, if the chamber was built prior to the state's PVHO law provided you have the ASME U-1 form. Otherwise, probably not.

3. SCOPE & APPLICATION

a) "..hyperbaric chambers and associated facilities that are used, or intended to be used, for MEDICAL APPLICATIONS and EXPERIMENTAL PROCEDURES at PRESSURES FROM 0 TO 100 PSIG .." (14.1 1.1.12)

b) All health care facilities other than home care (1.3.1.)

c) NFPA 99 rules are NOT intended to be "unmoveable".

d) 1.4.2 Alternative systems, methods, or devices approved as equivalent by the AHJ shall be recognized as being in compliance with this code.

e) 1.4.3 The AHJ shall be permitted to grant exceptions to this code. (Example: if you need/want to use an edition later than the one formally adopted by your AHJ—ask.)

D. NFPA 99 Chapter 1 (All editions)

1. Effective Date (1.6.1). The yearly edition of the document used is not determined by the NFPA. All questions related to applicability shall be directed to the authority having jurisdiction (AHJ).

2. New editions of NFPA 99 are usually adopted by action of a local "authority having jurisdiction". These actions tend to run several years behind code publication dates. Example: As of 1999 the City of New York was still enforcing the 1987 edition. NY state currently enforces 2002 edition. See Attachment A for a current adoption summary.

3. Know what edition your jurisdiction has adopted and is 'enforcing! Ignorance can be costly and/or embarrassing. When in doubt, ask your local Fire Marshall.

4. Discretionary Powers of Authority Having Jurisdiction (1.4.3) The authority having jurisdiction shall be permitted to grant exceptions to this code.

5. If you want to be able to use the 1999, 2002 or 2005 provisions and your jurisdiction (usually state level) is still enforcing an earlier edition, you may need to appeal to the local Fire Marshall or other enforcing agency for an exemption (usually granted).

E. Principal Supporting Documents.

ASME PVHO-1 Safety Standard for Pressure Vessels for Human Occupancy

NFPA 70 National Electrical Code

NFPA 53 Guide on Fire Hazards in Oxygen-Enriched Atmospheres

NFPA 50 Standard for Bulk Oxygen Systems at Consumer Sites

NFPA 55 Compressed Gases and Cryogenic Fluids Code (Where referenced, supercedes NFPA 50)

NFPA 101 Life Safety Code

F. Classes of Chambers

1. Classes

Class A: Human, Multiple Occupancy

Class B: Human, Single Occupancy

Class C: Animal Use Only

Class D: Altitude Chamber, Not Oxygen Enriched (99B)

Class E: Altitude Chamber, Oxygen Enriched (99B)

2. What happens as the lines between monoplace and multiplace blur?

3. Until the next edition of NFPA 99 (2015 or later), a chamber rated by the manufacturer as a single occupant chamber is a Class B chamber and has to meet restrictive electrical rules which presume an oxygen environment.

4. Presently, the only way to avoid the Class B electrical limitations is to build a chamber to Class A requirements (air environment, fire suppression system, etc.)

5. NOTE: 2 or more persons in a Class B chamber is "off-label" use.

G. Building / Facility Requirements

1. MONOPLACE CHAMBER FACILITIES (CLASS B CHAMBERS)

a) 1993 Code Edition:

(1) Exclusive use requirement applies to all chambers.

(2) No other requirements.

b) 1996, 1999, 2002, 2005, 2012 Code Editions:

(1) Room required to be for exclusive use of the hyperbaric operation only when used for hyperbaric procedures.

(2) Service equipment permitted to by located in multi‑ use spaces.

(3) Sprinkler protection required in the chamber room unless not contiguous to a health care facility or in a mobile facility. (To protect the facility from a fire originating in the hyperbaric area)

2. MULITPLACE CHAMBER FACILITIES (CLASS A CHAMBERS)

a) All Editions:

(1) 2 Hour fire-rated perimeter on portions of chamber room common to other spaces in the building. Not req'd on exterior walls. (To protect the hyperbaric facility from a fire originating elsewhere in the facility.)

(2) Sprinkler protection required in the chamber room unless not contiguous to a health care facility or in a mobile facility. (To protect the chamber operators and the hyperbaric facility from a fire originating within the hyperbaric area.)

b) 1996, 1999, 2002, 2005 & 2012 Code Editions:

(1) Room required to be for exclusive use of the hyperbaric operation only when used for hyperbaric procedures.

(2) Service equipment permitted to be located in multi‐ use spaces.

H. Major Ed-to-Ed Changes

1. 1999 Ed.: Major changes in electrical req'ts for Class A chambers based on a change in the target threat from the ignition of combustible vapors to the ignition of combustible solids.

2. 2002 Ed: Extensively reformatted to conform to Manual of Style req'ts. Significant changes in selected areas.

3. 2005 Ed.: Added egress time req'ts, smoke hoods for monoplace attendants, some other chgs

4. 2012 Ed.: Reformatted as a code instead of a standard. Clarified oxygen reserve req'ts, clarified boundaries between Ch. 5 and PVHO piping rules, confusion re hyperbaric air compressors req'ts (14.2.1.6 require Ch. 5 rules , 14.2.4.2.7 says "not necessarily so". Lithium & lithium ion batteries prohibited, low power lasers permitted.

I. Illumination

1. 1999, 2002, 2005 & 2012 Code Edition Requirements: External lighting is required where possible

a) Internal lights must be rated for 1.5 times maximum chamber pressure and have a maximum surface temperature of 185 degrees F.

b) Permanently installed lights must meet Class I, Division 1 or 2 requirements.

c) Ballasts must be located outside the chamber.

d) Portable lights must meet the rules for lights, battery operated devices or cord connected devices as appropriate. Power limitations for battery operated devices are 12VDC & 48W. This is a LOT of power!!!

2. Important Notes:

a) Acrylic plastic is opaque to infrared radiation. It is also a thermal insulator. Incandescent lamps close to acrylic plastic quickly cause overheating of the plastic.

b) Acrylic plastic is opaque to ultraviolet radiation and is degraded by high intensity ultraviolet radiation such as that which is found in sunlight. If fluorescent lights are used, consideration must be given to the amount and intensity of the UV radiation emitted by them. Beware of new "full spectrum" fluorescent lights. There is some evidence that normal window glass does not offer reliable UV protection.

J. Air Compressors and Purity

1. Applicability: Multiplace chambers and air ventilated monoplace chambers only.

2. Special Note: Monoplace chambers when used with air ventilations require at least Grade E air (req'd by 2012 ed, earlier ed. permitted Grade D which permits some water. Monoplace chamber controls do not tolerate water very well.

3. 1999 Code Edition

   a) Oil lubricated compressors permitted, but required to have an air purification system capable of producing medical air as defined by NFPA 99, Chapter 2.

   b) Sampling frequency:

      (1) Continuous monitoring of CO and volatized hydrocarbon levels downstream of the filtration package when oil lubricated compressors used.

      (2) When other types of compressors used, no requirements other than a requirement for periodic (every few months) sampling.

   c) When air compressors are used exclusively to supply a hyperbaric facility, they need only satisfy Chapter 19 requirements. If supplying medical air to piped gas systems as well, they must also meet the Chapter 4 (med gas) req'ts

4. 2002 Edition:

   a) Rules are a mess. Ch: 20 ? Must produce medical air

   b) Ch: 3 "Definitions" ? Medical air definition is a "non-definition"

5. 2005 Edition:

   a) Section 20.2.4.2 rules are sensible. Similar to 1999 rules

6. 2012 Edition:

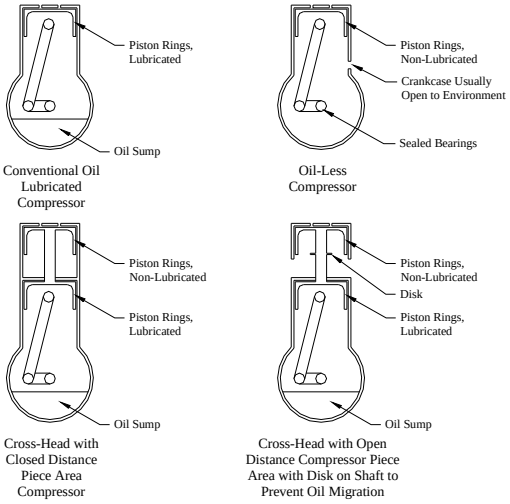
   a) Section 14.2.4.2 "Sources of Air" remains similar to 1999 and identical to 2005 req'ts. Monitoring req'ts in 14.2.8.6, req'ts for CO & Hydrocarbon monitoring in 2005 ed. dropped.

   b) Section 14.2.1.6 "Hyperbaric Medical Air System Req'ts" seems to invoke Ch. 5 medical air rules.

   c) Ch. 5 rules require add'l redundancy and monitoring req'ts, drier air and prohibit oil-lubricated compressors which Ch. 14 permits.

   d) Result =. Confusion. Use prior editions where possible

Types of Air Compressors



K. Fire Suppression "Architecture"

1. Monoplace:

   a) Suppression assumed to be impractical due to nearly pure O2 environment. Fire protection strategy is based completely on ignition prevention.

   b) Florida fire indicted that suppression may be possible, but so far no changes in technology or rules.

2. Multiplace:

   a) Minimize fire risk to extent possible, but permit most normally req'd medical devices and reasonable patient comforts

   b) Have a robust suppression system based on solid research

   c) Effectiveness of NFPA compliant system proven in service

L. Fire Suppression: Multiplace

1. Handline and deluge systems are required to be independent meaning no single item whose failure could knock both systems out of service.

   a) Both the deluge system & handlines operating from the same water tank water is not a permitted design.

2. Deluge system response time must be faster than 3 seconds.

3. Both deluge & handline systems must be functionally tested at least very 6 months. Periodic exercise of the deluge system and all other fire suppression system controls is essential to system safety.

4. System manufacturer must provide the purchaser with deluge spray pattern TEST results. Spray pattern test must be repeated if system design changed. (You are entitled to data that shows your system meets the rules.)

M. External Chamber Electrical

1. All Editions: 1993-2012 Protection Architecture
    a) Generally governed by normal NEC rules
    b) Electrical circuits necessary for the safe termination of a dive are required to be waterproof and fitted with drains so that they are not subject to being disabled by the building sprinkler system.
2. Oxygen Piping And Electrical Items In Same Space (14.2.7.3.17.4)
    a) If possible, avoid this situation.
    b) If you must, space must be continuously ventilated or monitored for excessive oxygen concentration.
3. Application: Mostly to multiplace, but also to later model mono chambers with electronic controls.

N. Storage & Handling of Gases

1. Gas Storage (14.3.4.1.3)- Storage and handling of compressed air, oxygen and other medical gases are required to meet "applicable" requirements of Chapter 5. This requirement is contained in an obscure location in Chapter 20 and is often overlooked. Also now addressed in NFPA 55. Storage req'ts for have changed with each of the 1996, 1999 , 2002 , 2005 & 2012 editions.
2. Inlet Filters (14.2.9.3)– Filters are required at or near the point connection for all gas input points to the facility from commercially supplied cylinders (Filtration req'ts are: 1996 ed & earlier-none, 1999 to 2005 ed - 10 microns or finer, 2012 ed – 66 microns.)
3. A least one fire is known to have been caused by debris associated with commercially supplied cylinders.
4. HP gas whips with 45 micron filters on inlets available.

O. Egress (Exit) Requirements

1. Multiplace chambers: Be able to be depressurized from 3 ATA to ambient pressure (door open) in less than 6 minutes.
2. Monoplace chambers: Be able to be depressurized from 3 ATA to ambient pressure (door open) in less than 2 minutes.
3. All chambers:
    a) How to deal with a possible incapacited operator situation?
    b) Fire drills are req'd at least annually and must be documented. (2012, 14.3.1.4.5). Note: The controls for the emergency depressurization valves on most monoplace chambers are spring-return-to-close and generally cannot be simultaneously operated by a single operator.

P. Operator Breathing Apparatus

1. Multiplace chambers (14.2.4.5.3): SCBAs or air-line masks req'd for console operators (all code editions). Be aware of triggering OHSA fit testing req'ts.

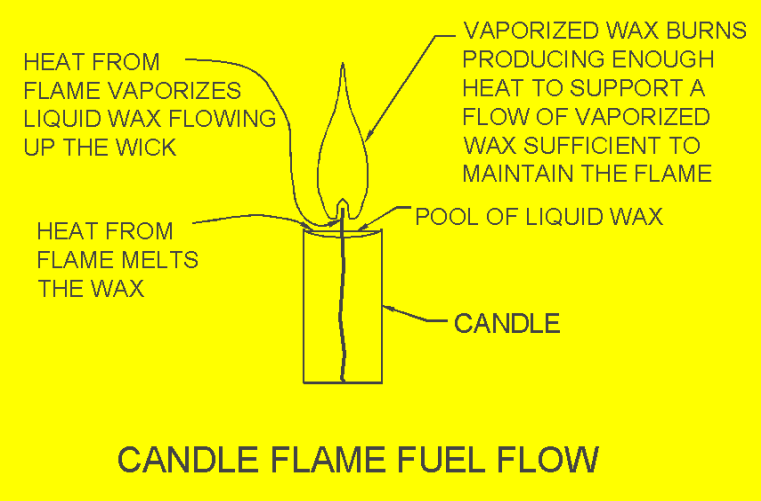
2. Monoplace Chambers (14.2.4.5.3): 2005 & 2012 ed of NFPA 99 require escape breathing apparatus (or better) req'd to be available for monoplace chamber operators. No req't in earlier editions, but still a good practice. One inexpensive option is escape breathing apparatus as currently used in high rise buildings and large naval vessels. If you have a multiple monoplace facility, do you know how long it would take to safely remove all patients in event of a fire or smoke situation? 14.2.4.5.4 requires you to know this time.

III. Section 3: NFPA 99, Electrical Rules.

A. Electrical Devices – Multiplace

1. 1993 and 1996 Code Editions - PRIMARY THREAT TAKEN TO BE FLAMMABLE VAPORS
2. 1999 Code Edition - Protection Architecture - PRIMARY THREAT TAKEN TO BE: COMBUSTIBLE LIQUIDS AND SOLID MATERIALS
3. This is a much lower risk environment than is assumed by prior editions and permits the use of electrical safety rules which are much less restrictive.

Why Surface Temperatures Matter



B. Electrical Devices – Multiplace

1. 1999-2012 EDITIONS - PROTECTION ARCHITECTURE

a) Low Voltage, Low Power Equipment (14.2.7.3.16): (speakers, communication, sensor leads, etc.)

(1) Must be isolated from mains power.

(2) Non-enclosed wires must be on an intrinsically safe circuit or limited to 28 V and 0.5 A under both normal and fault conditions.

(3) Speaker circuits are limited to 28 volts rms and 25 watts and the speakers must employ designs where both the circuitry and wiring are enclosed.

(4) Battery operated headsets must meet the requirements for battery operated devices.

b) Patent Care Related Devices (14.2.7.3.17*, A 14.2.7.3.17):

(1) General construction req'ts of other sections

(2) Req'ts specific to cord connected devices

(3) Req'ts specific to battery operated devices

(4) Add'l req'ts (much "good stuff") on equipment used in a chamber in 14.3.2.1. (low power lasers ok, prohibitions on pocket warmers, certain metals & devices, etc.)

c) Patent Care Related Devices-General (14.2.7.3.17*):

(1) Appliances handling O2 must not allow O2 accumulation in spaces housing electrical / electronic items. (14.2.7.3.17.4)

(2) Surface temperatures must not exceed 85°C (185°F) (14.2.7.3.12)

(3) Must not represent implosion or explosion hazard. (14.2.7.3.1)

(4) "All equipment shall be rated, or tested and documented, for intended hyperbaric conditions prior to use." (14.2.7.3.2)

(5) NOTE: By whom is not specified! The Safety Director, NRTL?

(6) If devices contain cooling fans or other air moving devices, those devices MUST be checked for overloading under hyperbaric conditions. Fan power requirements increase linearly with atmospheric density.

(7) Keypads and all other device functions must be checked for proper operation under hyperbaric conditions.

d) Patent Care Related Devices - Battery Operated (14.2.7.3.17.5):

(1) Batteries must be sealed, non-offgassing, suitable for the chamber operating pressure and enclosed during use.

(2) Batteries may not be charged or changed in the chamber.

(3) Equipment electrical ratings not to exceed 12V and 48W. (LOTS of power.)

(4) Lithium and lithium ion batteries prohibited unless app'd for hyp. use by mfr or NRTL.

(5) 1999-2012 Rules: Battery Operated Devices

(a) Electrical Devices – Multiplace

e) Patent Care Related Devices - Cord Connected (14-2.7.3.17.6):

(1) Must be turned on and off by means on an on-off switch.

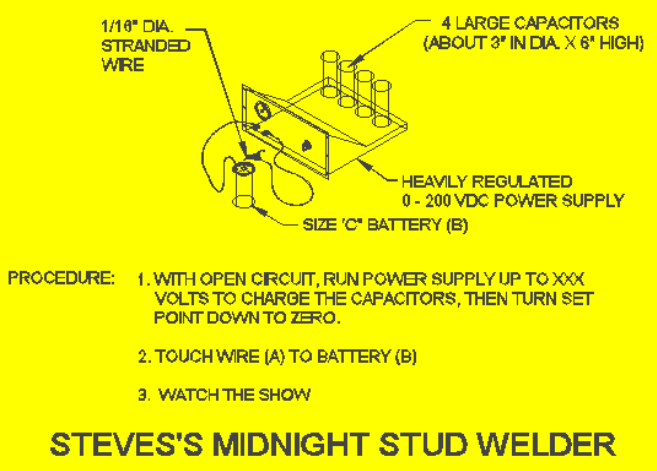
(2) Equipment electrical ratings shall not exceed 120V and 2A unless the electrical portions are inert gas purged. (LOTS of power.)

(3) Receptacles (power outlets) must meet req'ts of 14.2.7.2.10.

(4) 1999-2012 Ed: Cord Connected Devices

(a) Many commonly used medical monitoring devices will meet the new rules for use inside Class A (multiplace)

Something That Would Not Meet the Rules



C. Electrical Devices – Monoplace

1. 1999-2012 EDITIONS

a) Protection architecture: Req'ts same as Class A req'ts PLUS:

b) Electrical Equipment in Monoplace Chambers (14.2.7.6).

(1) Functions limited to communications equipment and patient physiological monitoring (14.2.7.6.1)

(2) Elec leads to chamber interior are limited to 28 V and 4.0 W power transmissions (0.5w prior ed).

(3) Device surface temperatures limited to 50°C (122°F).

c) Lighting to be from external sources only (14.2.7.6.2).

d) Air Environment Monoplace: Subject to the same electrical requirements as the 100% oxygen monoplace.

e) No prohibition against batteries! Should they be permitted ?? Cell phones prohibited by 14.3.1.5.1

D. Grounding Req'ts & O2 Fraction

1. Multiplace Chambers

a) Chamber must be connected to electrical ground. (14.2.7.4.1) Max. resistance between chamber and ground point <1 ohm.

b) Permanently installed furniture must be grounded (14.2.9.1)

c) Anti-static procedures and patient grounding required if oxygen fraction exceeds 23.5%. (14.3.1.5.3).

d) NOTE: This is the ONLY place where NFPA 99 provides specific limit for the oxygen fraction in a multiplace chamber in editions prior to 2012. 2012(14.2.8.4.2.1) now requires audible & visual alarms if O2 fraction > 23.5%

2. Monoplace Chambers(20-2.7.4.1)
    a) Same as for multiplace chambers.
3. Patient Grounding (14.2.1.5.3.2):
    a) Req'd to be by a high impedance (1 Meg) conductive pathway.
        (1) Only a very small current is required to dissipate a static charge.
        (2) A low resistance connection exposes the patient to an electric shock hazard should he/she come into contact with an electric power source while connected to the ground point.
        (3) Many operators feel patient grounding is unnecessary or can be done in other ways.
        (4) Req'd only when oxygen fraction above 23.5%
    b) Caution - Ground connections require periodic testing. Paint, corrosion film, lubricants, etc. can provide uninvited insulation and spoil what was at one time an effective ground.

E. Facility Electrical Power
1. Hazardous Conditions should not occur as a result of either (14.2.7.2.6):
    a) Loss of normal power
    b) Resumption of power
    c) Examples of "hazardous conditions" are loss of pressure control, loss of supervisory alarm function, spurious alarms, deluge activation, loss of comms, etc.
2. Some form of back-up power is req'd for essential functions.
3. Stored air sufficient to complete normal operations will, in most circumstances, avoid a requirement for the facility air compressors to be supplied with emergency power (14.2.7.2.5).

F. Current Issues
1. Who is the person, organization or entity authorized to "bless" equipment for use under hyperbaric conditions per 14.2.7.3.2?? The facility Safety Director is given authority to prohibit potentially hazardous equipment by 14.3.1.3.2*
2. The rules are so new that few persons or organizations in the HBO industry are familiar with them.
3. The fire risks of this new environment must be understood and appreciated. Devices are now permitted that can be overheated if their cooling is sufficiently disrupted. Should overtemperature shutdowns be a requirement?

IV. Section 4: Fire Risk Management

A. What Makes a Fire in a Chamber Such a Big Deal?
1. Small amount of energy can make the interior very hot
    a) One T-shirt can represent a sufficient supply of combustible material.
2. Smoke and CO accumulation
    a) Most of the patients killed in the 1999 fire in Italy died of CO poisoning.

3. Fast development
    a) Typically only a few seconds from ignition to total involvement of the chamber interior
4. Flight is not possible in the time available
    a) Chamber occupants must remain in the same vicinity as the fire.

B. Fire Risk Management: The Main Elements (* covered elsewhere)
1. Know the Threats
2. Prevention Procedures (*)
3. Suppression Capability (*)
4. Response Procedures (*)
5. Practice and Maintenance (*)

C. Know the Threats!
1. Oxygen Level
2. Instruments that Lie
3. Potential Fuels
4. Ignition Sources (and their effect on fire development)

D. Useful Information Sources:
1. NFPA 99 Chapter 14 "Hyperbaric Facilities"
2. NFPA 99, Annex B "Additional Explanatory Notes", Section B.14
3. NFPA 52, Guide on Fire Hazards in Oxygen Enriched Environments
4. NFPA Healthcare Facilities Handbook
5. Hyperbaric Chamber Safety

E. A Possible Threat Rating System
1. This system is subjective but based on experience.

    ! = one unit of risk, much like one bullet in 6-bullet revolver in a game of Russian Roulette.

    Risk units from each of the four threat areas add.

    !!!!!! = 6 simultaneous risk units $\rightarrow$ asking for trouble

    !!!!!!! = 7 simultaneous risk units $\rightarrow$ better hope the fire system works

F. Threats: Chamber Oxygen Level
1. As pO2 levels increase:
    a) Ignition temperatures and energies drop
    b) Flame spread rates increase

2. See NFPA 52 & Hyperbaric Chamber Safety for technical details.

Circumstance	**Threat Contribution:**
Normoxic air	!
Compressed air at 6 ATA	!!
100% oxygen (any pressure)	!!!

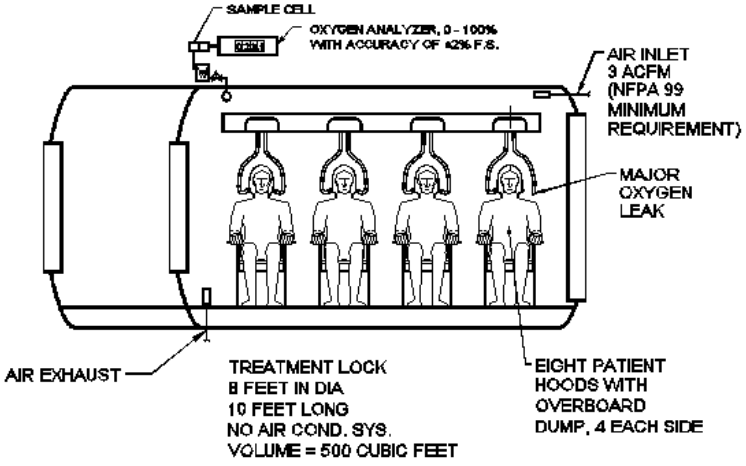
G. Threats: Room Oxygen Level

1. Monoplace chambers dump a "chamber-full" of oxygen into to room every time you remove a patient.
2. If room is small, or ventilation poor, and the chambers are busy, you can elevate the oxygen fraction in the room. Examples:
   a) Trailer environments
   b) Off-hours ops with the building ventilation shut down.

H. Threats: Instruments that Lie

Circumstance	Threat Contribution:
Potentially non-uniform atmosphere (*)	
Recent studies have indicated the oxygen from a major leak can pool if the chamber atmosphere is not "well stirred" (Tech Course 2002)	!!
Poor quality oxygen monitoring system (*)	!

* "Air" environment chambers only



I. ANSWERS

1. "Ventilation Time Constant" much too low permitting potentially highly non-uniform atmospheric compositions to develop.

   "Ventilation Time Constant (VTC)" = $\frac{\text{Chamber Volume}}{\text{Ventilation Rate}}$

   Ventilation rate = supply air flow + ACS flow (if any)

   Ventilation time constant is the number of minutes for the total ventilation flow into the chamber from all sources to equal the chamber volume.

   In diving chambers a VTC of less than 10 is normally required to achieve minimally decent control of chamber temperature and humidity for personnel comfort. A life support system with a 100 acfm blower installed on a chamber with a volume of 1,000 cubit feet (8 feet diameter by 20 feet long) results in a VTC of 10. Most saturation chambers have a VTC of less than 5.

   The VTC in the example shown is 167.

   If the oxygen level readings are to be credible, the chamber atmosphere must be sufficiently "stirred" to ensure a reasonably uniform composition. Research directly addressing this issue of "how well stirred is good enough" has not yet been done. However, a VTC of 167 is unlikely to achieve the desired result.

2. Poor Quality Oxygen Analyzer Installation

   a) Accuracy: When the tolerable oxygen concentration range is between 21% and 23.5% an oxygen analyzer with a range of 0 - 100% and an accuracy rating of +/- 2% of Full Scale is not a really good idea. The "saving grace" in most situations is fact that the units are regularly calibrated at the 21% point.

   b) Response Time. Use a good quality analyzer, and be mindful of the response time.

   c) Sample Cell Pressure. Nearly all gas analyzers sense partial pressure and convert the reading to per cent on the ASSUMPTION that the sample cell is at atmospheric pressure. If the sample cell pressure varies, especially if between calibration and operation, the operating reading will be off.

J. Threats: Ignition Sources

Circumstance	Threat Contribution:
Limited energy & one time sparks	!
Sustainable high temperature ignition sources	!!
Low temperature ignition sources	!!!

K. Limited Energy & One Time Sparks

1. Threat Contribution = !
2. Usually dangerous only in the presence of combustible vapors or when exceptionally high energy. Nonetheless, they are frightening, especially in the presence of 100% oxygen.
3. Examples:
    a) Most static sparks
    b) Percussion sparks (e.g. metal-to-metal contact)
4. Static sparks rarely occur in the atmospheres where the relative humidity levels is above 50% .

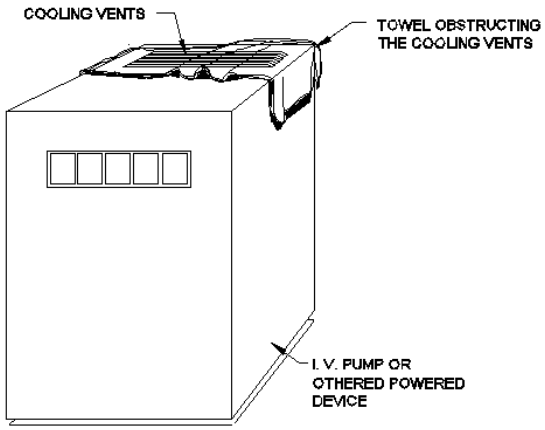
L. Sustainable High Temperature Ignition Sources

1. Threat Contribution = !!
2. Sustainable sparks, electrical shorts, resistance coils, etc.
3. Examples:
    a) Capacitor discharges
    b) Line power shorts
    c) Igniters used in most hyperbaric chamber fire tests to date
4. Typically produce a small well behaved fire that does not spread rapidly (comment re: recent YouTube video re "fire test" in inflatable chambers)

M. Low Temperature Ignition Sources:

1. Threat Contribution = !!!
2. Examples:
    a) Hot surfaces:
    b) Housings for incandescent lamps
    c) Overloaded motors
    d) Hot plates
    e) Powered devices of nearly any kind with sufficiently bad cooling system failure
    f) Dieseling in a contaminated compressed air line
    g) Friction heating from the flow of supersonic gas past an obstruction (can occur when grit gets imbedded in valve seats or seals)
3. Can precede flame initiation with generation of substantial amounts of vaporized fuel. Also pre-heats remaining unvaporized fuels. Flame development, once initiated, can be very rapid.

N. Threats: Potential Fuels



Circumstance	Threat Contribution:
Combustible vapors	!!!!!
Combustible liquids and powers	!!!!
Combustible solids	! to !!

1. Potential Fuels: Combustible Vapors
   a) Threat Contribution = !!!!!
   b) Already vapor.
   c) Any significant accumulation is VERY dangerous.
   d) Examples: flammable anesthetics alcohol vapors
2. Combustible Liquids and Powers
   a) Threat Contribution = !!!!
   b) Easily converted to vapor form. Keep to absolute minimum.
   c) Generally safe in quantities that are sufficiently small relative to the size of the chamber. See NFPA 99, Para 20-3.1.5.2 for guidance.
   d) Examples:
      (1) containers of medicinal alcohol
      (2) alcohol swabs
      (3) finely divided combustible powders such as iron filings, grain dust

3. Potential Fuels: Combustible Solids

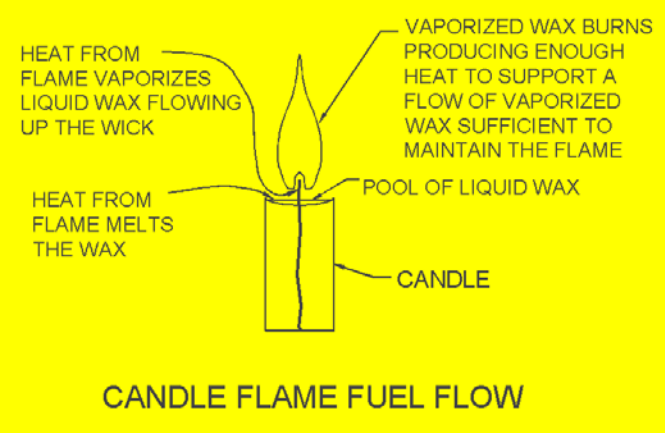
   a) Require sustained heat to vaporize in quantity.

   b) Unavoidable, but safe when used with care.

   c) Generally safe examples (threat contribution = !): most natural fiber clothing paper in the form of books and magazines seat cushions and covers paint over thick gauge metals such as a chamber shell

   d) Situations to be Avoided (threat contribution = !!): thick paint over very thin gauge metal adrift papers in loose single sheet form

O. Threats: Potential Fuels + Pre-Heat



V. Conclusion