MEMORANDUM

TO: NFPA Technical Committee on Hyperbaric and Hypobaric Facilities

FROM: Jeanne Moreau-Correia

DATE: March 2, 2010

SUBJECT: NFPA 99 A11 ROP Letter Ballot

The ROP letter ballot for NFPA 99 HEA-HYP 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
3.3.50* Flame Resistant. The property of a material that passes the small-scale test in NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films.

A.3.3.50 Flame Resistant. A source of ignition alternate to the gas burner specified in NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films, could be required for this test if it is to be performed in 100 percent oxygen at several atmospheres pressure.

NFPA 99 should not adopt the preferred definition of flame resistant from NFPA 99B and should eliminate the misleading term "flame resistant". This will require changes in some significant changing of terminology throughout NFPA 99 and 99B in several sections.

Note that the fire tests committee has long changed the title of NFPA 701, which is now called "Standard Methods of Fire Tests for Flame Propagation of Textiles and Films" and no longer uses the term "flame resistant". Moreover, the concept of flame resistance, which is misleading, has been eliminated from all (or almost all) NFPA documents. NFPA 701 also no longer has a "small scale test". It should also be noted that NFPA 701 is not applicable to many of the materials for which the term is used in NFPA 99, including interior finishes and conductor insulations.

The definition contained within NFPA 99B, which reads as follows: "Where flame resistance of a material is required by this standard, that material shall pass successfully the small-scale test, except that the test shall be conducted in the gaseous composition and maximum pressure at which the chamber will be operated." has three problems: (a) it uses a term that should be replaced by the concept of meeting the requirements of the appropriate test in NFPA 701, (b) it addresses a test that no longer exists (small scale test in NFPA 701) and (c) it contains requirements which are best not used in a definition.

Sections of NFPA 99 using the flame resistant concept are: 3.3.126, 20.2.2.5, 20.2.2.5.2, 20.2.7.3.6, 20.3.1.5.4.1, 20.3.2.4, 20.3.6.2.2.4, A.3.3.50, A.20.2.2.5.2, A.20.3.1.5.4, C.20.1.1.3.1.

NFPA 101 has replaced the concept of “flame resistant” by the concept of meeting “the flame propagation performance criteria contained in NFPA 701”. This type of concept should be used for those locations where NFPA 701 is applicable.

Recommended actions will be proposed for all sections listed above.

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
3.3.126 Nonflammable. An adjective describing a substance that will not burn under the conditions set forth in the definition of flame resistant.

3.3.126 Nonflammable. (1) Not readily capable of burning with a flame. (2) Not liable to ignite and burn when exposed to flame. Its antonym is flammable.

The existing definition in NFPA 99 is inappropriate as materials can be flammable and still “pass” the NFPA 701 test, which is what is being considered by “flame resistant”. The NFPA preferred definition of “nonflammable” is contained in NFPA 921 and is appropriate for general use within NFPA and for consistency. It is recommended that the NFPA 921 definition be adopted.

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Committee Meeting Action: Accept in Principle

Revise to read:
Nonflammable. Not readily capable of burning with a flame and not liable to ignite and burn when exposed to flame.

Committee Statement: The term "Its antonym is flammable" is not needed.

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.

3.3.133 Oxygen-Enriched Atmosphere. An atmosphere containing more oxygen than normal air, which contains 20.95% oxygen; for the purposes 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.

The existing definition in NFPA 99 would be enhanced by adding the generic concept. The NFPA preferred definition, from NFPA 1670, is probably inappropriate as it is also too limiting.

Oxygen-Enriched Atmosphere. (preferred) NFPA 1670-2004

Air atmospheres containing more than 23.5 percent oxygen by volume at one standard atmosphere pressure.

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 in Principle

3.3.133* Oxygen-Enriched Atmosphere (OEA). For the purposes of this code, an atmosphere in which the concentration of oxygen exceeds 23.5 percent by volume. (HYP)

A.3.3.133 For additional information see A.3.3.14.3 and Figure A.3.3.14.3.

Committee Statement: NFPA 99 is now a Code and this is reflected in the definition. The reference to A.3.3.14.3 is for additional information.

See 3.3.129 in the preprint.
Add a section on "medical device approval" for Class A, B, and C hyperbaric chambers. To be added to Annex A or C, or put into a new Annex. The proposed new wording is as follows:

Insert Artwork Here 99_L52_R.doc

Substantiation: The clinical hyperbaric community is in need of such a guidance document.
Committee Meeting Action: Reject
Committee Statement: Not appropriate for publication in this document since other documents such as ISO 15001, Anesthetic and Respiratory Equipment-Compatibility with Oxygen, address risk analysis for equipment.

Add new 20.1.1.2 to read as follows:
Portions of this chapter shall apply to existing facilities (see 1.1.12.2).
This clarifies that portions of this apply to existing facilities.
Committee Meeting Action: Accept
Committee Statement: See 14.1.1.2 in the preprint.

Add text to read as follows:
20.2.1.1.2 Class B & C chambers located inside a building shall not be required to be protected by 2 hour fire resistance rated construction.
Renumber existing 20.2.1.1.2.
Substantiation: This clarifies that a Class B and C chamber inside a building does not need a 2-hour fire-rated wall.
Committee Meeting Action: Accept
Committee Statement: See 14.2.1.1.2 in the preprint.
FORWARD:

This program is intended to establish criteria for selection, testing, modification, documentation and approval of a medical device for use in a specific class A (multipurpose) hyperbaric chamber. It is to be a “living” document, which requires regular review and editing. The administrative and operational uniqueness of your facility, the configuration and capabilities of your class A chamber, and the local codes and laws for the year your class A hyperbaric chamber was put into service must be addressed in the editing process.

The primary goal is to insure the safety of patients and staff. After reviewing, editing and approving the new facility specific program, each device should go through the series of steps outlined in this document before final approval.

Any italicized text bracketed with [ ___ ] should be replaced with the requested information.

This form is free of copyright and is to be used at the sole responsibility and discretion of the end user.

Please delete this page as part of the editing process to make this document facility and chamber specific.

It is suggested that the Safety Director (SD) be the primary responsible party for editing this document. The responsibilities of the SD, as outlined in NFPA 99, make this person the logical choice.

A. The SD should have access to and a through understanding of the following recommended resource materials.
   1. 510(k) or PMA summary information on the device being considered for inclusion to the facility's medical device inventory. Food and Drug Administration, US Government.
   2. FDA Center for Devices and Radiological Health's web site http://www.fda.gov/cdrh/
   5. Medical device's user manual.
   6. NFPA 70: National Electrical Code, edition [ latest year publication ], Articles 500 and 700, National Fire Protection Association. 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9904.
   8. NFPA 99: Standard For Health Care Facilities, edition [ year being enforced by the local fire marshal or authority having jurisdiction ], National Fire Protection Association. 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9904.

B. Prior to starting the program for the first time the SD should do the following.
   1. Determine the structure of the equipment selection committee and who the members will be.
   2. Decide what members will have signoff approval. All members will receive a copy of the final decision packet.
   3. Edit the program to meet the administrative and operational uniqueness of your facility, the configuration and capabilities of your class A chamber, and the applicable local codes and laws for the present year.
   4. Have members with signoff approval review and signoff on program content.
   5. Orient each member of the equipment selection committee on the selection, testing, modification, documentation and approval process.

C. Ongoing considerations the SD should keep in mind.
   1. Network with their peers at other facilities of similar size, equipment usage and management matrix.
   2. Attend technical meetings where this topic is on the agenda. This will also give the SD an opportunity to discuss the topic informally with other attendees.
   3. Prepare for the future obsolescence of the medical devices in the facility's present inventory.

D. Once a request has been submitted for medical device approval, the SD should do the following.
   1. Review and update the program. Things to keep in mind: change in facility ownership, new equipment selection committee member, change in chamber configuration, new chamber, change in codes or laws, new industry standard and have your networking efforts resulted in new information that impacts the present program content.
   2. Have members with signoff approval review and signoff on all updates.
   3. Establish a working rapport with the sales representative. Inform them of the uniqueness of getting their medical device approved by your facility for use inside your chamber. Be truthful. You're not looking for an approval letter from the manufacturer, but a conversational means of getting technical information from their biomedical engineer.
   4. Have the sales representative make the introductions with a biomedical engineer from the manufacturer that is willing to answer technical questions from the SD and the biomedical engineer that supports your present medical device inventory. Be truthful. Ask focused questions, but understand they can not tell you how to make their device hyperbaric safe. That is your team's job.
   5. Using the resources available (staff knowledge, industry contacts and hard copy references) the SD should make a preacceptance survey to see if the medical device has a reasonable chance of being approved.

E. Once a medical device is determined by the SD to be a suitable candidate, the SD should do the following.
   1. Notify each member of the equipment selection committee.
   2. Involve the appropriate people in the testing, documentation and modification phase of the process. Use all your resources to insure a positive result.

F. Once the medical device has passed all testing criteria, the SD should do the following.
   1. Have each member of the equipment selection committee with signoff responsibility sign the approval letter.
   2. Have all other members sign receipt of the testing packet and give them a copy of the signed approval letter.
### EQUIPMENT SELECTION COMMITTEE

<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>SIGN-OFF</th>
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<tbody>
<tr>
<td>HBO2 Safety Director</td>
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<td>Yes</td>
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<td>HBO2 Program Director</td>
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<td>Yes</td>
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<tr>
<td>HBO2 Medical Director</td>
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<td>Yes / No</td>
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<tr>
<td>Facility Administrator</td>
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<td>Yes</td>
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<tr>
<td>Facility Director of Biomedical Engineering</td>
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<td>Yes / No</td>
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<tr>
<td>Facility Biomedical Engineer</td>
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<td>Yes / No</td>
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<tr>
<td>Facility Risk Manger</td>
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<td>Yes / No</td>
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<tr>
<td>Facility Safety Director</td>
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<td>Yes / No</td>
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### MEDICAL DEVICE SEEKING APPROVAL

<table>
<thead>
<tr>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Medical device name</td>
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<tr>
<td>Model number</td>
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<tr>
<td>Serial number</td>
<td>[N/A unless full test performed per device]</td>
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<tr>
<td>Type of device</td>
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<tr>
<td>Sales representative’s name</td>
<td></td>
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<tr>
<td>Sales representative’s phone #</td>
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<tr>
<td>Manufacturer’s biomedical engineer</td>
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<tr>
<td>Manufacturer’s biomedical engineer’s phone #</td>
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<td>Is the device being used at any other facility?</td>
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<td>What modifications, if any did they have to make to meet their acceptance criteria?</td>
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<td>How does their criteria differ from yours?</td>
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<td>Will that difference preclude possible acceptance?</td>
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<tr>
<td>Is the manufacturer’s sales person cooperative?</td>
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<tr>
<td>Is the manufacturer’s biomedical engineer cooperative?</td>
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<td>Is device 100% solid state, including switches?</td>
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<td>If no, can arc potential be removed?</td>
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<tr>
<td>Electrical rating- AC: volts</td>
<td>NFPA limit- [insert value]</td>
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<tr>
<td>amps</td>
<td>NFPA limit- [insert value]</td>
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<tr>
<td>watts</td>
<td>NFPA limit- [insert value]</td>
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<tr>
<td>Is the device going to use AC power in the chamber?</td>
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<td>Does device’s plug match chamber receptacle?</td>
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<td>Does device’s electrical cord meet NFPA 99?</td>
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<td>Electrical rating- DC: volts</td>
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<td>Amps</td>
<td>NFPA limit- [insert value]</td>
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<td>Watts</td>
<td>NFPA limit- [insert value]</td>
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<tr>
<td>Do batteries meet NFPA 99?</td>
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<td>Expected battery life at ambient pressure</td>
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<tr>
<td>Does device have any enclosed gas filled spaces?</td>
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<tr>
<td>Enclosed gas filled spaces #1</td>
<td>[can they be vented?]</td>
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<tr>
<td>#2</td>
<td>[can they be vented?]</td>
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<tr>
<td>Does this device meet NFPA 99 for the year’s standard that is being enforced by the local AHJ?</td>
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<td>Does this device meet NFPA 99 for the latest edition?</td>
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<tr>
<td>Does the SD foresee any major obstructions to gaining approval for this device?</td>
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### CLASS A HYPERBARIC CHAMBER

<table>
<thead>
<tr>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Medical device name</td>
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<td>Model number</td>
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<td>Serial number</td>
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<td>Manufactured per ASME PVHO-1</td>
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<td>Working pressure</td>
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<td>Medical device hull penetrators (type &amp; size)</td>
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<td>#4</td>
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<tr>
<td>Is chamber wired to support 110V equipment?</td>
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TESTING MODULE

Note:
1. Device should be prominently labeled “NOT For Patient Use” prior to testing.
2. If the device proves not to be fit for hyperbaric use and is to be put back into the general medical device inventory, it must first be checked by a biomedical engineer. The “NOT For Patient Use” label can then be removed.
3. If approved for hyperbaric use, the “NOT For Patient Use” label should be replace with a “HBO2 Only” label. Even though it can be used at normobaric pressure, the device should be stored in the hyperbaric area.
4. The equipment selection committee should make a decision as to the level of testing across the same model. Below are two suggested choices.
   a. Each device will go through the complete approval process.
   b. Once a device is approved for use, any future requests for approval of the same device (same manufacturer, model and series) will go through an abbreviated testing module. The device should be modified in the same manner as the first model, but the test can be limited to a reduced set of functions. This abbreviated list of functions should be decided by the safety director in conjunction with a biomedical engineer.
5. If the decision is made to limit the use of a medical device to less than the deepest treatment profile the class A chamber is rated to, there should be a policy written to prevent that device from inadvertently being used at that depth.

FACILITY POLICY ON EQUIPMENT MODIFICATION

Potential Choices:
1. Internal policy.
   a. Use what you have now.
   b. Use this document as a framework to build on.
   c. Use another non-proprietary program.
2. US Navy Experimental diving Unit (NEDU) testing guidelines and/or results data.
   a. This information may be difficult to get, but the Navy is working on allowing the public freer access to their data.
   b. The Navy does not certify equipment. They test and approve equipment for US Navy use only.
3. Hartford Steam Boiler.
   a. This company is rumored to be willing to test equipment using your criteria.
   b. Their fee may be beyond many facilities’ budgets.

Document that you followed your policy.

WHY AND HOW THE DEVICE WAS MODIFIED

1. The following modification(s) were made prior to testing. Note: Experience has shown that moderate to large unvented gas filled spaces will not pass the pressure phase of testing and can irreversibly damage the equipment.
   a. 
   b. 
   c. 

2. Failed function # __. Following modification performed to address failure.
   a. 
   b. Function # __ passed / failed post modification.

3. 

JUSTIFICATION FOR MODIFICATION (Risk / Benefit analysis)

1. No medical device that performs the needed task is marketed for class A hyperbaric chamber use.
2. Device is essential to patient care.
3. 
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FUNCTION LIST DIRECTIONS

1. Use medical device’s operator’s manual to establish a list of functions (testing data points). Type each function in above. For functions with a range, break them down into #[ ]a, #[ ]b, and #[ ]c. How you determine what three data points within the function to use will depend on the device’s usage. One suggestion is that “a” = a commonly used data point at the low end of the range, “b” = the data point of [(a + c) / 2] and “c” = a commonly used data point at the high end of the range.

2. If more than 21 functions, duplicate page above and edit function numbers.

<table>
<thead>
<tr>
<th>Function</th>
<th>Outcome: pass / fail</th>
<th>Action for failed outcome:</th>
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<tr>
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Testing Log

Pressure:                  pg of

Int.
TESTING LOG DIRECTIONS

1. Function: Function numbers should correspond to the function list. Remember, those functions with a range will have 3 testing points (a, b and c).
2. Outcome: pass/fail: To receive a passing mark the device must pass both for function and accuracy (i.e., an IV pump set to deliver 20ml/hr passes the function if it delivers fluid and passes the accuracy if it delivers 20ml/hr within the device's listed +/- tolerance). Log "pass" or "fail" in this column. All failed outcomes need to be documented in the "why and how the device was modified" section of this document.
3. Action for failed outcome: Summarize action taken for failed outcome in this column. Document detailed information on action taken in the "why and how the device was modified" section of this document. Once corrective action is taken, the test must be redone.
4. Int.: The tester needs to initial each function checked.
5. Repeat test for each treatment pressure used by your facility. For example: 45 fsw, 60 fsw and 165 fsw.
6. If more than 21 functions, duplicate page above and edit function numbers.

[ Institution's letterhead ]

MEDICAL DEVICE APPROVAL LETTER

The [ manufacturer ] [ medical device name ] [ model # ] [ serial # ] has been approved by the following equipment selection committee members for the [ specify the specific chamber ] class A hyperbaric chamber used at [ facility name ]. The below members also acknowledge receipt of a copy of this letter and the completed approval packet for the above-mentioned medical device.

Hyperbaric Program Director Date

Hyperbaric Safety Director Date

Facility Administrator Date

[ other involved party ] Date

The following equipment committee members acknowledge receipt of a copy of this letter and the completed approval packet for the above-mentioned medical device. (I ___ page document)

Facility Director of Biomedical Engineering Date

Hyperbaric Medical Director Date

Facility Risk Manager Date

Facility Safety Director Date

Facility or Contracted Biomedical Engineer Date

[ other involved party ] Date

It is my hope that those that choose to use this document provide feedback on its usefulness using the contact information below.

For an electronic copy of this document, please e-mail your request to the address below. Please include your name and contact information.

William J. Davison, CHT
Program Director
Hyperbaric Medicine Center
Presbyterian/St. Luke's Medical Center

Oxyheal Health Group
1719 East 19th Avenue
Denver, Colorado 80218
(303) 839-6903
colorado@oxyheal.com
20.2.1.2.1 Class A, Class B, or Class C chambers not contiguous to a health care facility, and located in a mobile vehicle-mounted facility shall not be required to be protected as specified in 20.2.1.2.

Delete text as follows:

20.2.1.3 The room or rooms housing Class B and Class C chambers shall be afforded sprinkler protection in accordance with 20.2.1.2.

Delete text as follows:

20.2.1.3.1 Chambers not contiguous to a health care facility, and located in a mobile vehicle-mounted facility shall not be required to have sprinkler protection as specified in 20.2.1.2.

Substantiation: There are duplicate requirements for Class A and other classes of chambers. Combining them cleans up the standard.

Committee Meeting Action: Accept
Committee Statement: See 14.2.1.2 and 14.2.1.2.1 in the preprint.

CGA philosophical position: reserve supply systems should not necessarily be required for all levels of hyperbaric chamber systems.

Substantiation: There is too much confusion regarding the supply of oxygen to hyperbaric systems. Chapter 20 does not include any direction in this matter. The main issue is whether a reserve supply is necessary for all hyperbaric installations.

This is not original material; its reference/source is as follows:
NFPA 55, 2005

Committee Meeting Action: Accept in Principle
See 14.2.1.4 in the preprint.
20.2.1.4 Nonflammable gases shall be permitted to be piped into the hyperbaric facility.

20.2.1.4.1 Shut-off valves accessible to facility personnel shall be provided for such piping at the point of entry of the room housing the chamber.

20.2.1.4.2 Storage and handling of nonflammable gases shall meet the applicable requirements of Chapter 5, Gas and Vacuum Systems, of this document and NFPA 50, Standard for Bulk Oxygen Systems at Consumer Sites.

20.2.1.4 Medical Gas and Vacuum System Requirements

20.2.1.4.1 General. Where medical gases are installed, they shall conform to the requirements for the appropriate level. Systems conforming to different levels within the same building are permitted. The appropriate level shall be determined as follows:

(1) All systems shall comply with Level 1 requirements if any part of the systems are Level 1, except under both of the following conditions:
   (a) The system(s) is entirely separate from the Level 1 system(s) (i.e., is stand-alone) and is not connected to Level 1 sources or distribution pipelines.
   (b) The occupancy to be served and the function of that occupancy is distinct from other occupancies in the building.

(2) Medical gas and vacuum systems shall be permitted to be Level 2 systems only where both of the following conditions exist:
   (a) Paragraphs 20.2.1.4.1(1)(a) and 20.2.1.4.1(1)(b) apply.
   (b) Patients served by the system(s) are not dependent on mechanical ventilation or assisted mechanical ventilation at anytime, including during administration of anesthesia.

(3) Medical gas and vacuum systems shall be permitted to be Level 3 systems only where both of the following conditions exist:
   (a) Paragraphs 20.2.1.4.1(1)(a) and 20.2.1.4.1(1)(b) and 20.2.1.4.1(2)(a) apply.
   (b) The patient population, during or subsequent to treatment, are not dependent for life on the gases or vacuum system(s), and the treatment(s) that the facility will perform can be completed without detrimental effect on patient outcomes in the event of sudden loss of the gas or vacuum system(s).
   (c) The total of all gases in cylinders or containers, except nitrogen, connected and in storage at one time does not exceed 85 m³ (3000 ft³) at STP, except that 142 m³ (5000 ft³) at STP shall be permitted if oxygen is stored in a DOT Specification 4L (cryogenic liquid) cylinder.
   Note: If the total gas in cylinders or containers, except nitrogen, connected and in storage at one time does exceed 85 m³ (3000 ft³) at STP, or that 142 m³ (5000 ft³) at STP shall be permitted if stored in a DOT Specification 4L (cryogenic liquid) cylinder, the central supply system shall follow Level 1 or Level 2 requirements for Central Supply Systems.
   (d) The system(s) supplies not more than two adjoining single treatment facilities.

20.2.1.4.2 Storage and Handling. Storage and Handling of medical gas and vacuum shall meet the applicable requirements of Chapter 5, Gas and Vacuum Systems, of this document and NFPA 55.

Substantiation: Too much confusion regarding this issue.

Chapter 20 does not include a decision tree as does chapters 13, 14, 17, and 18.

The main issue is whether a reserve supply is necessary for a hyperbaric installation. Taking the same approach as chapters 13, 14, 17, and 18 will allow the facility to define the level of care that will be performed inside the hyperbaric chamber. This level of care will decide how the central supply should be designed.

CGA’s M-1 requires that for hyperbaric medical gases sources for healthcare facilities - “reserve systems are required for respiratory and hyperbaric use.”

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

NFPA 55, 2005 edition

Committee Meeting Action: Accept in Principle
[Delete and replace existing 20.2.1.4 with below]

20.2.1.4 Hyperbaric Piping Requirements.

20.2.1.4.1 Except where otherwise required by this chapter, piping systems dedicated to the hyperbaric chamber shall meet the requirements of ANSI/ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy, for hyperbaric facility piping systems.
20.2.1.4.2 [Renumber 20.2.1.4.1 and insert existing text] Shuttoff valves accessible to facility personnel shall be provided for such piping at the point of entry to the room housing the chamber(s).

20.2.1.5 Hyperbaric Medical Oxygen System Requirements.

20.2.1.5.1 Where medical oxygen systems are installed for hyperbaric use, the hyperbaric area(s) or facility shall be treated as a separate zone.

20.2.1.5.2 Chapter 5 Gas and Vacuum Systems requirements shall apply to the medical oxygen system for hyperbaric use, from the source of supply to the first in-line valve located downstream of the zone valve(s).

20.2.1.5.3 ANSI/ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy requirements shall apply to the medical oxygen system for hyperbaric use, starting immediately downstream of the first in-line valve located after the zone valve(s).

20.2.1.5.4 General. Where an oxygen system is installed for hyperbaric treatments, it shall comply with the requirements for the appropriate level as determined below.

20.2.1.5.4.1 Hyperbaric oxygen system, for acute and non-acute care, connected directly to a hospital's oxygen system shall comply with 5.1 Level 1 Piped Gas and Vacuum Systems, as applicable, of this document, except as noted below.

A. Central Supply Systems. Oxygen systems shall comply with 5.1.3.4 as applicable except as follows:
1. An emergency oxygen supply connection (EOSC) is not required for the hyperbaric oxygen system.
2. An In-building emergency reserve (IBER) is not required for the hyperbaric oxygen system.

20.2.1.5.4.2 Hyperbaric stand-alone oxygen system, for acute care, shall comply with 5.1 Level 1 Piped Gas and Vacuum Systems, as applicable, of this document, except as noted below.

A. Central Supply Systems. Oxygen systems shall comply with 5.1.3.4 as applicable except as follows:
1. An emergency oxygen supply connection (EOSC) is not required for the hyperbaric oxygen system.
2. An In-building emergency reserve (IBER) is not required for the hyperbaric oxygen system.

B. Warning Systems. Oxygen systems shall comply with 5.1.9 as applicable except as follows:
1. Warning systems shall be permitted to be a single master/area alarm panel.

20.2.1.5.4.3 Hyperbaric stand-alone oxygen system, for non-acute care, shall comply with 5.2 Level 2 Piped Gas and Vacuum Systems, as applicable, of this document, except as noted below.

A. Central Supply Systems. Oxygen systems shall comply with 5.2.3.4 as applicable except as follows:
1. If the operating oxygen supply consist of high pressure cylinders designed with a primary and secondary source, no reserve supply is required.
2. If the operating oxygen supply consists of liquid containers designed with a primary and secondary source, a min of 1 hour supply for the reserve is required.
3. If the operating oxygen supply consists of a bulk primary, a reserve with a minimum of 1 hour supply is required.
4. An emergency oxygen supply connection (EOSC) is not required for the hyperbaric oxygen system.
5. An In-building emergency reserve (IBER) is not required for the hyperbaric oxygen system.

20.2.1.6 Storage and Handling of Medical Gases

20.2.1.6.1 [Renumber 20.2.1.4.2 and insert] Storage and handling of medical gases shall meet the applicable requirements of Chapter 5, Gas and Vacuum Systems, of this document and NFPA 55, Standard for the Storage, Use, and Handling of Compressed Gases and Cryogenic Fluids in Portable and Stationary Containers, Cylinders, and Tanks. Definition (new): Hyperbaric stand-alone oxygen system: The oxygen system is entirely separate from the hospital's Level 1 Oxygen System, or is a freestanding Hyperbaric Facility.

Delete section 20.3.4.1.3.

Substantiation: If the proposed language above is accepted, this paragraph is redundant.

Delete section 20.3.4.1.4 (2nd sentence).

Substantiation: If the proposed language above is accepted, this paragraph is contradicts the paragraph.

Reword section 20.3.4.1.4 (1st sentence): Replace the word compressed with medical, and add NFPA 55. Also, renumber to 20.3.4.1.3 (we are deleting the existing 20.3.4.1.3).

The requirement should read:
The requirements set forth in Section 5.1 and NFPA 55 concerning the storage, location, and special precautions required for medical gases shall be followed.

Committee Statement: This language is more appropriate for hyperbaric facility applications. The word compressed
is not used in Chapter 5 to describe gases; medical gas is the preferred term. NFPA 55 is the industry document for Oxygen bulk gas locations and design and cylinder storage. This change will be consistent with this document. See 14.2.1.4 in the preprint.

99-486     Log #CP121     HEA-HYP
(20.2.1.5, 20.2.1.6)    Final Action: Reject

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Add new section 20.2.1.6 as follows:
20.2.1.6 Hyperbaric Medical Air System Requirements
20.2.1.5.1 Where medical air systems are installed for hyperbaric use, the hyperbaric area(s) or facility shall be treated as a separate zone.
20.2.1.5.2 Chapter 5 requirements shall apply to the medical air system for hyperbaric use, from the source of supply to the first in-line valve located downstream of the zone valve(s).
20.2.1.5.3 ANSI/ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy, requirements shall apply to the medical air system for hyperbaric use, starting immediately downstream of the first in-line valve located after the zone valve(s).
20.2.1.5.4 General. Where a medical air system is installed for hyperbaric treatments, it shall comply with the requirements for the appropriate level as determined in 14.2.1.5.4.1 through 14.2.1.5.4.7.
20.2.1.5.4.1 Hyperbaric medical air system for acute and nonacute care connected directly to a hospital’s medical air system shall comply with Section 5.1, as applicable.
20.2.1.5.4.2 Reserved
20.2.1.5.4.3 Hyperbaric stand-alone medical air system for acute care shall comply with Section 5.1, as applicable.
20.2.1.5.4.4 Reserved
20.2.1.5.4.5 Warning Systems. Medical Air systems shall comply with 5.1.9 as applicable except that warning systems shall be permitted to be a single master/area alarm panel.
20.2.1.5.4.6 Hyperbaric stand-alone medical system, for nonacute care shall comply with Section 5.2, as applicable, except as noted in 14.2.1.5.4.7.
20.2.1.5.4.7 Central Supply Systems. Medical Air systems shall comply with 5.2.2.5 as applicable except as follows:
(1) Medical Air Compressor System - Medical air compressors, dryers, aftercoolers, filters, and regulators shall be permitted to be simplex.
(2) Medical Air Cylinder System – A gas cylinder header per 5.1.3.5.9 with sufficient cylinder connections to provide for at least an average day’s supply with the appropriate number of connections being determined after consideration of delivery schedule, proximity of the facility to alternate supplies, and the facility’s emergency plan shall be permitted.
20.2.1.5 Storage and Handling of Medical Gases. Storage and handling of medical gases shall meet the applicable requirements of Chapter 5 and NFPA 55, Compressed Gases and Cryogenic Fluids Code.

Substantiation: Medical air systems are needed for hyperbaric facilities and these requirements outline what is required.

Committee Meeting Action: Reject

Committee Statement: This proposal is not appropriate for hyperbaric facilities as the need for this type of medical air is different from a traditional medical air system per chapter 5.
Technical Committee on Hyperbaric and Hypobaric Facilities,

**Recommendation:** Add a new sub-paragraphs to section 20.2.2.1* as follows:

20.2.2.1.1* Piping systems for hyperbaric facilities shall be required to meet only the requirements of this Chapter and section “Piping” of ANSI/ASME PVHO-1.

20.2.2.1.2. Piping that is installed in concealed locations in the building housing the hyperbaric facility, such as inside building walls or above false ceilings, shall use only those joining procedures permitted by Chapter 5 “Gas and Vacuum Systems” of this Standard.

A.20.2.2.1.1. Hyperbaric chamber systems often require piping materials, pressure ratings and joining techniques that are not permitted by Chapter 5 “Gas and Vacuum Systems” of this Standard.

**Substantiation:** Some local authorities having jurisdiction have been requiring all field installed piping to be performed under the requirements of Chapter 5 “Gas and Vacuum Systems” of this Standard. Further, they have been requiring the work to be performed by locally licensed med gas plumbers. This is not always appropriate, and was not the intent of this Chapter.

**Committee Meeting Action:** Accept

**Committee Statement:** See 14.2.2.1 in the preprint.
Recommendation:

20.2.2.5 The interior of Class A chambers shall be unfinished or treated with a finish that is one of the following:

1. Inorganic-zinc–based
2. High-quality epoxy
3. Flame resistant – Meets a Class A flame spread index in accordance with Chapter 10 of NFPA 101

20.2.2.5.1 If the interior of a Class A chamber is treated (painted) with a finish listed in 20.2.2.5, the cure procedure and minimum duration for each coat of finish to off-gas shall be in accordance with the manufacturer’s application instructions and material safety data sheets.

20.2.2.5.2* If sound-deadening materials are employed within a hyperbaric chamber, they shall be flame resistant as defined in Chapter 3 and meet a Class A flame spread index in accordance with Chapter 10 of NFPA 101.

A.20.2.2.5.2 Many commercial sound-deadening materials that might be flame resistant exhibit adequate fire performance are porous and will absorb water from activation of the fire-suppression system and retain odor. Metallic panels that contain a large quantity of small holes or are made of wire mesh and are installed about 1 in. (2.5 cm) away from the chamber wall can be used to form an acoustic baffle. These panels should be made from corrosive-resistant materials such as stainless steel or aluminum and can be painted in accordance with 20.2.2.5.1.


Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). Interior finishes cannot be tested using NFPA 701 but should be tested to ASTM E 84 (Steiner tunnel test) or to NFPA 286 (room-corner test). The way to test and the pass-fail criteria are contained within Chapter 10 of NFPA 101 or of NFPA 5000. The term flame resistant is associated with NFPA 701.

The technical committee should decide what fire performance should be required for the interior finish materials, if the committee believes that Class A is too restrictive.

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 in Principle in Part

Revise Section 20.2.2.5 to read as follows:

20.2.2.5 The interior of Class A chambers shall be unfinished or treated with a finish that is one of the following:

1. Inorganic-zinc–based
2. High-quality epoxy
3. Flame resistant – Noncombustible material as defined in 3.3.125

20.2.2.5.2* If sound-deadening materials are employed within a hyperbaric chamber, they shall be flame resistant as defined in Chapter 3 and limited combustible material as defined in 3.3.98.

Committee Statement: Deletion of the term fire resistant is appropriate. Revised wording refers to defined terms in the standard.

See 14.2.2.5 in the preprint.

Technical Committee on Hyperbaric and Hypobaric Facilities,

**Recommendation:** Revise Section 20.2.4.2.5 to read as follows:

20.2.4.2.5 Air compressor installations shall consist of two or more individual compressors with capacities such that required system flow rates can be maintained on a continuous basis with any single compressor out of operation unless 20.2.7.2.4 20.2.7.2.5 is satisfied.

**Substantiation:** Editorial.

**Committee Meeting Action:** Accept

**Committee Statement:** See 14.2.4.2.5 in the preprint.

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Technical Committee on Hyperbaric and Hypobaric Facilities,

**Recommendation:** Add a new Section 20.2.4.4.3 to read as follows:

20.2.4.4.3 For Class B chambers equipped with a breathing apparatus, the breathing apparatus shall function at all pressures that can be encountered in the chamber.

**Substantiation:** Many hyperbaric programs provide air breaks to patients as an integral part of the treatment profile. Breathing masks used in this manner should be verified for proper function before use.

**Committee Meeting Action:** Accept

**Committee Statement:** See 14.2.4.4.3 in the preprint.

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Technical Committee on Hyperbaric and Hypobaric Facilities,

**Recommendation:** Add a new Section 20.2.4.5.4 to read as follows:

20.2.4.5.4 The time required to evacuate all persons from a hyperbaric area with a full compliment of chamber occupants all at treatment pressure shall be measured annually during the fire training drill required by Section 20.3.1.4.5.

20.2.4.5.4.1 The "occupants" for this test shall be permitted to be simulated.

A.20.2.4.5.4 The intent of this requirement is to run a realistic drill. Treatment pressures should be appropriate to the facility's operations.

**Substantiation:** Experience from the UHMS Accreditation Program has demonstrated that the evacuation time is often both not known and much longer than facility personnel realize.

**Committee Meeting Action:** Accept

**Committee Statement:** See 14.2.4.5.4 in the preprint.
20.2.5.1.9* The hyperbaric fire suppression systems shall be required to meet only the requirements of this chapter.
20.2.5.1.9.1 The fire protection system shall not be required to meet NFPA 13 requirements for deluge systems.
20.2.5.1.9 Fire suppression systems for hyperbaric chambers have unique and specific requirements that are not addressed by NFPA 13. Further, NFPA 13 contains some provisions that are not appropriate to hyperbaric chambers. Hyperbaric chamber system fire suppression systems built to the requirements of NFPA 99, Chapter 20 have been found to be effective and sufficient for the application.
20.2.5.1.10 Hyperbaric manufacturers shall be allowed to install, test and permit fire suppression systems engineered and hydraulically calculated by fire protection engineers.
A.20.2.5.1.10.1 A signed and stamped certificate from the fire protection engineer shall be accepted as documentation for approved installation.

Substantiation: NFPA 99 provides specific guidelines for fire suppression system performance and construction. However, it does not provide any requirements or guidance regarding who is allowed to install the systems and what credentials the installers are required to possess. Given this situation, there are instances where the local authorities having jurisdiction have been refusing to accept the deluge portion of a hyperbaric chamber fire suppression system unless it was designed in accordance with NFPA 13 and installed by a fire suppression system installer licensed in their jurisdiction. This is not the intent of NFPA 99, Chapter 20 requirements.

Committee Meeting Action: Reject
Committee Statement: The committee has rejected this proposal but will investigate NFPA 13 further and will address this issue again in the ROC stage.

20.2.7.2.5 When reserve air tanks or nonelectric compressor(s) are provided to maintain ventilation airflow within the chamber and supply air for chamber pressurization, the compressor(s) and auxiliary equipment shall not be required to have an alternate source of power.

Substantiation: The revised wording was editorial for readability.
Committee Meeting Action: Accept
Committee Statement: See 14.2.7.2.5 in the preprint.
20.2.7.3.6 Conductor Insulation. All conductors inside the chamber shall be insulated with a material classified as flame resistant as defined in Chapter 3, which meets an appropriate fire performance in accordance with NFPA 70.

Insulation for conductors cannot be tested by NFPA 701 but should meet the appropriate requirements of NFPA 70, National Electrical Code. The NEC will address the requirements for the application. The term flame resistant is associated with NFPA 701.

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 in Principle in Part

Strike "as defined in Chapter 3", do not accept the reference to NFPA 70. The section now reads as follows:

Conductor Insulation. All conductors inside the chamber shall be insulated with a material that is flame retardant or fire resistant.

Flame resistance is no longer defined in Chapter 3. A specific reference in NFPA 70 is needed.

See 14.2.7.3.6 in the preprint.

(7) Lithium and Lithium Ion batteries shall not be allowed in the chamber during chamber operations unless the product has been approved for use in hyperbaric conditions by the manufacturer.

Lithium Ion batteries burn explosively when short circuited, crushed or damaged. In the closed environment of the hyperbaric chamber this could be fatal. This concern is supported by several sources; Computer and Computer Peripheral Fires with a Discussion of Batteries, Marty Ahrens Fire Analysis and Research division, NFPA Aug. 2006 and Aviation Incidents Involving Smoke, Fire or Explosion, FAA, Batteries and Battery powered Devices, Nov 2006. Other types of batteries have also been implicated in fires. Lithium Ion has a greater potential than other types of batteries and therefore should be specifically prohibited. Lithium has been prohibited in hyperbaric conditions in at least one document; International Marine Contractors Association, IMCA D 041, Use of Battery Operated Equipment in Hyperbaric conditions, Oct 2006. The Lithium Ion batteries should be allowed in the hyperbaric chamber if the manufacturer provides design and testing for use in the increased pressure environment.

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

NFPA Fire Analysis and Research Division, FAA Website, IMCA Website.

Committee Meeting Action: Accept in Principle

Revise the proposed language as follows:

(7) Lithium and lithium ion batteries shall be prohibited in the chamber during chamber operations unless the product has been accepted or listed for use in hyperbaric conditions by the manufacturer or a nationally recognized testing agency.

Committee Statement: Editorial. See 14.2.7.3.17.5(7) in the preprint.
Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Revise to read as follows:

20.2.7.6.1.1 Circuits shall be designed to limit the electrical energy to wire leads into the chamber under normal or fault conditions to no more than 28 V and 0.5 W. This requirement shall not exclude more stringent requirements imposed by other Codes governing electromedical apparatus.

Substantiation: Test work (“Safety Requirements for Electronic Sensors in Oxygen Enriched Atmosphere at Pressures up to 4 atm.[3 bar]”, Radiometer A/S) performed since publication of the present-day rule suggest that requirements for electrical apparatus used in oxygen enriched atmospheres might be similar to requirements for intrinsically safe apparatus. The 4 watt and 28 volt limitation is within the requirements for safety in Groups A and B (Hydrogen) gases (the most stringent group) and is well below the spark ignition data of the Radiometer study. The proposed new limits should therefore provide an adequate safety margin for Class B chamber fire safety while still allowing room for designers of the communications and patient monitoring functions allowed in Class B chambers by paragraph 20.2.7.6.1. The second sentence should be included so that the requirement of the first sentence, which is aimed toward fire safety, is not construed to preclude other patient apparatus requirements which are aimed toward patient electrical safety and which may be more stringent than one or both of the voltage or wattage requirements proposed for fire safety.

Committee Meeting Action: Accept
Committee Statement: See 14.2.7.6.1.1 in the preprint.

Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Revise to read as follows:

20.2.7.6.3 No electrical circuit in a Class B chamber shall operate at a temperature exceeding 60°C (140°F). No materials shall be allowed in a Class B chamber whose temperature exceeds 50°C (122°F) nor shall any electrical circuit inside a Class B chamber operate at a temperature exceeding 50°C (122°F).

Substantiation: The orientation of this requirement is shifted from fire safety to patient burn prevention. The present 60 degree requirement was felt to be adequate for fire safety; however, this temperature likely exceeds the temperature for burn prevention, especially when considering the cramped environment for a patient inside a Class B chamber. I urge the Committee to use their experience and judgement regarding the proposed new temperature limitation to revise it as they see fit for patient burn safety. My one data point is from the Shriner’s Burn Institute which states that serious burn (scald) can occur from contact with water for a period somewhat over 5 minutes.

Committee Meeting Action: Accept
Committee Statement: See 14.2.7.6.3 in the preprint.
Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Revise text in section 20.2.8.6 as follows:

20.2.8.6* Chamber Gas Supply Monitoring.

20.2.8.6.1 Air from compressors shall be sampled at least annually. The air supply of Class A and Class B chambers shall be sampled for concentrations of carbon monoxide.

A.20.2.8.6 The purity of the various gas supplies should be assured. It is recommended that air be sampled at the air intake location at times when the intake air is likely to have maximum impurities (e.g., when vehicles or stationary engines upwind of the intake are running):

A purity statement for any cryogenic or high pressure cylinder gas should be supplied by the vendor. Gas cylinder purity statements should be cross referenced, where possible, with the delivered gas. For additional verification, some facilities have installed sampling ports for monitoring oxygen and other gases.

Substantiation: The intent to protect from carbon monoxide exposure is addressed in 20.2.8.6.1. Sampling at the air intake location is inappropriate.

Committee Meeting Action: Accept
Committee Statement: See 14.2.8.6 in the preprint.

Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Revise text as follows:

20.2.8.6.2* As a minimum, the air supplied to Class A chambers shall meet the requirements for CGA Grade E.

20.2.8.6.3 As a minimum, the air supplied to Class B chambers shall meet the requirements for CGA Grade E with the additional limit of no condensable hydrocarbons.

Substantiation: This should be changed to Grade E. Grade E air is more appropriate for hyperbaric applications. Grade D air is acceptable for SCBA use at 1 ATA. Grade E is the standard for SCUBA air used at greater than 1 ATA. The only real difference between the two (and the primary issue) is the allowed CO2 content (Grade D allows 1000ppm, Grade E allows 500ppm). Elevated CO2 is a greater issue at depth than at the surface. There is also an annex note that should be addressed.

Committee Meeting Action: Accept
Committee Statement: See 14.2.8.6.2 and 14.2.8.6.3 in the preprint.

Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Add a new Section 20.2.8.6.4 to read as follows:

20.2.8.6.4 When cylinders are used to provide breathing air in Class A or B chambers, the gas shall be medical air USP.

20.2.8.6.5 When cylinders are used to provide oxygen in Class A or B chambers, the gas shall be oxygen USP.

Substantiation: Numerous examples exist in the gas industry where the contents of a certified cylinder are not actually what it has been certified to be. Also, there are numerous examples of wrong labeling etc. Independently verifying the contents of a cylinder before connecting it to a breathing system will help minimize the risk of providing the wrong gas to a patient.

Committee Meeting Action: Accept
Committee Statement: See 14.2.8.6.5 in the preprint.
99-501  Log #CP113  HEA-HYP
(20.2.9.2.1 (New) )  Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation:  Add a new section 20.2.9.2.1 to read as follows:
   20.2.9.2.1 Each Class B chamber shall have an independent exhaust line.
Substantiation:  Clarification of requirements between Class A and B chamber exhaust lines.
Committee Meeting Action:  Accept
Committee Statement:  See 14.2.9.2.1 in the preprint.

99-502  Log #CP105  HEA-HYP
(20.2.9.3)  Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation:  Revise Section 20.2.9.3 to read as follows:
   20.2.9.3 The supply piping for all air, oxygen, or other breathing mixtures from certified commercially supplied flasks
cylinders and portable containers shall be protected by a particulate filter of at least 66 microns or finer.
Substantiation:  10 microns is too restrictive and clarification of the intent of a flask is needed. 66 microns is consistent
with CGA standards.
Committee Meeting Action:  Accept
Committee Statement:  See 14.2.9.3 in the preprint.
20.3.1.5.4.1 Silk, wool, or synthetic textile materials shall not be permitted in Class A or Class B chambers unless the fabric meets the flame propagation performance criteria of NFPA 701 resistant requirements of 20.3.1.5.4.5.

20.3.1.5.4.5 Where flame resistance is specified, the fabric shall meet the requirements set forth for the small-scale corresponding test in NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films, in an atmosphere equivalent to the maximum oxygen concentration and pressure proposed for the chamber.

Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). It is appropriate to use NFPA 701 in this instance, but the correct terminology should be used. Moreover, there is no “small-scale test” in NFPA 701. The test to be used will be a function of the weight per unit area of the fabric to be tested. The term flame resistant is associated with NFPA 701.

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 in Principle

Revise Section 20.3.1.5.4.1 to read as follows:

20.3.1.5.4.1 Except where permitted in 20.3.1.5.4.2, Silk, wool, or synthetic textile materials shall not be permitted in Class A or Class B chambers unless the fabric meets the flame resistant requirements of 20.3.1.5.4.5.

Add a new item #6 to Section 20.3.1.5.4.3 as follows:

20.3.1.5.4.3 The physician or surgeon in charge, with the concurrence of the safety director, shall be permitted to use prohibited items in the chamber that are one of the following:

(1) Suture material
(2) Alloplastic devices
(3) Bacterial barriers
(4) Surgical dressings
(5) Biological interfaces
(6) Synthetic textiles

Delete Section 20.3.1.5.4.5 as follows:

20.3.1.5.4.5 Where flame resistance is specified, the fabric shall meet the requirements set forth for the small-scale test in NFPA 701, Standard Methods of Fire Tests for Flame Propagation of Textiles and Films, in an atmosphere equivalent to the maximum oxygen concentration and pressure proposed for the chamber.

Committee Statement: The committee eliminated the reference to a specific test criteria and simply eliminated fabrics that can create a static discharge.

See 14.3.1.5.4.1 in the preprint.
Technical Committee on Hyperbaric and Hypobaric Facilities,

Recommendation: Revise Section 20.3.1.5.7 to read as follows:

20.3.1.5.7 Clothing worn by patients in Class A or B chambers and personnel in Class A chambers shall prior to each treatment, conform to the following:

1. Be issued by the hyperbaric facility or specifically approved by the safety director for hyperbaric use
2. Be uncontaminated
3. Be devoid of prohibited articles prior to chamber pressurization

Substantiation: Surveyors in the Undersea & Hyperbaric Medical Society's Clinical Hyperbaric Facility Accreditation Program have surveyed facilities that allow patients to wear personal clothing. In each case, approval to wear personal clothing was provided by the Safety Director prior to the first treatment with no assessment thereafter. It is not reasonable to expect that a patient will wear the same clothing during their course of therapy.

Committee Meeting Action: Accept
Committee Statement: See 14.3.1.5.7 in the preprint.

James Bell, Intermountain Health Care

Recommendation: Insert: High energy lasers shall not be used under any condition.

Substantiation: Lasers are used in low energy devices such as drip sensors, pulse oxymetry, etc. The concern with high energy devices does not exist with those devices. Temperature, voltage and other limitations of energy have been noted in other sections. We need to allow for low energy lasers.

Committee Meeting Action: Reject
Committee Statement: High energy versus low energy lasers are not defined.

Marcelo M. Hirschler, GBH International

Recommendation: Revise text to read as follows:

20.3.2.4 Equipment used inside the chamber requiring lubrication shall be lubricated with oxygen-compatible flame-resistant material.

Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). It is not appropriate to use NFPA 701 in this instance. It is recommended that the committee choose an appropriate fire test or even delete the requirements, which is unenforceable. The term flame resistant is associated with NFPA 701.

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 in Principle
Committee Statement: The word appropriate is not enforceable.
See 14.3.2.4 in the preprint.

99-507 Log #359 HEA-HYP
(20.3.6.2.2.4) Final Action: Accept in Principle

Submitter: Marcelo M. Hirschler, GBH International
Recommendation: Revise text to read as follows:
20.3.6.2.2.4 Lubricants shall be oxygen compatible and shall exhibit appropriate fire performance flame-resistant
Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). It is not appropriate to use NFPA 701 in this instance. It is recommended that the committee choose an appropriate fire test or even delete the requirements, which is unenforceable. The term flame resistant is associated with NFPA 701.

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Committee Meeting Action: Accept in Principle
See 14.3.6.2.1.4 in the preprint.

99-508 Log #CP103 HEA-HYP
(20.3.6.3) Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Change title to read as follows:
20.3.6.3 Fire Protection Equipment Inside Hyperbaric Chambers.
Substantiation: In a few jurisdictions, this standard is being taken out of context and applied to the general room fire suppression system. This was not the intent of this standard. By clarifying the title, it will be very clear to any AHJ that the requirements of this section are intended for the hyperbaric system.

Committee Meeting Action: Accept
Committee Statement: See 14.3.6.3 in the preprint.

99-521 Log #CP107 HEA-HYP
(A.20.2.9.2) Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Create annex note for A.20.2.9.2 as follows:
A.20.2.9.2 Exhaust piping extending from the building may create a lightning risk. Lightning protection should be considered.
Substantiation: Copper exhaust pipes extending out of a building could be a lightning rod.
Committee Meeting Action: Accept
Committee Statement: See A.14.2.9.2 in the preprint.
99-522 Log #400 HEA-HYP (A.20.3.1.3.2) Final Action: Accept in Principle

Submitter: James Bell, Intermountain Health Care
Recommendation: Insert: Electronic records that include a protected user and password will be accepted in place of a paper log.
Substantiation: The wording in the document needs to reflect changes in technology. There are several places in NFPA 99 chpt 20 that require a signature. We should allow for an electronic signature.
Committee Meeting Action: Accept in Principle
Revise the existing wording as follows:
A.20.3.1.3.2 The complexity of hyperbaric chambers is such that one person should be designated chamber operator, such as one in a position of responsible authority. Before starting a hyperbaric run, this person should acknowledge, in writing, in an appropriate log, the purpose of the run or test, duties of all personnel involved, and a statement that he or she is satisfied with the condition of all equipment. Exceptions should be itemized in the statement.
Safety, operational, and maintenance criteria of other organizations are published, for example, in the Undersea & Hyperbaric Medical Society Safety Committee documents and the Compressed Gas Association pamphlets, and should be reviewed by the safety director. The safety director should serve on the health care facility safety committee. Due to a conflict of responsibility, the same individual should not serve as both Medical Director and Safety Director.
Committee Statement: It is the intent of the committee to recognize other forms of maintaining a log other than in writing.
See A.14.3.1.3.2 in the preprint.

99-523 Log #CP111 HEA-HYP (A.20.3.1.3.2) Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Add the following:
A.20.3.1.3.2 The term of Safety Director is used for convenience. It is the intent of this section to establish a set of safety responsibilities for that person regardless of the job title.
Substantiation: There is confusion regarding this term, but it is important that the safety responsibility be given to some one regardless of the title.
Committee Meeting Action: Accept
Committee Statement: See A.14.3.1.3.2 in the preprint.

99-524 Log #CP109 HEA-HYP (A.20.3.1.5.1) Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Change text as follows:
A.20.3.1.5.1.1 The immediate vicinity of the chamber is defined as the area around the chamber from which activation of the flame detector can occur. Flame detectors can be prematurely activated by certain radiation sources. Oxygen-filled chambers dump oxygen into the room each time the door is opened at the end of a treatment. Oxygen could also be dumped into the room by the chamber pressure relief device. Air-filled chambers could leak oxygen into the room from the breathing gas piping. This oxygen enrichment lowers the ignition temperature of combustible materials. Therefore, extra caution should be used in the area around the chamber as well as inside the chamber.
Substantiation: Renumbering – this annex note should follow 20.3.1.5.1.1
Content – The current annex note seems to be about accidentally activating a flame detector. This is inconsistent with the section heading “Potential Ignition Sources”.
Committee Meeting Action: Accept
Committee Statement: See A.14.3.1.5.1.1 in the preprint.
A.20.3.1.5.4 It is recommended that all chamber personnel should wear garments of the overall or jumpsuit type, completely covering all skin areas possible, and as tightfitting as possible. It can be impractical to clothe some patients (depending upon their disease or the site of any operation) in such garments. Hospital gowns of flame resistant textiles meeting the flame propagation performance criteria of NFPA 701 should be employed in such a case.

Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). It is appropriate to use NFPA 701 in this instance, but the correct terminology should be used. Moreover, there is no “small-scale test” in NFPA 701. The test to be used will be a function of the weight per unit area of the fabric to be tested.

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Committee Meeting Action: Accept in Principle

Revise to read as follows:

It is recommended that all chamber personnel should wear garments of the overall or jumpsuit type, completely covering all skin areas possible, and as tightfitting as possible. It can be impractical to clothe some patients (depending upon their disease or the site of any operation) in such garments. Hospital gowns can be employed in such a case.

Committee Statement: The term flame resistant textile was deleted to be consistent with previous actions.

See A.14.3.1.5.4 in the preprint.
Definitions

1. **Combustion**: A chemical process of oxidation that occurs at a rate fast enough to produce heat in the form of either a glow or a flame.

2. **Flammable**: A combustible (solid, liquid, or gas) that is capable of easily being ignited and rapidly consumed by fire.

3. **Flash Point**: The minimum temperature of a liquid or solid at which it gives off vapor sufficient to form an ignitable mixture with oxygen under specified environmental conditions.

4. **Ignition Temperature**: The minimum temperature required to initiate or cause self-sustaining combustion under specified environmental conditions.

5. **Lower Explosive Limit (LEL) or Lower Flammable Limit (LFL)**: The minimum concentration of fuel vapor (percent by volume) over which combustion will occur on contact with an ignition source.

General Information.

Wound dressings are necessary inside hyperbaric chambers. They play an important role in infection control and patient outcome. Important safety concerns include: production of heat, production of static electricity, production of flammable vapor, ignition temperature, and total fuel load.

Many wound dressings employ fabrics and other materials that are gas-permeable. It is a common misconception that a gauze bandage will isolate an undesirable product from the chamber environment. However, gauze is gas-permeable and will allow oxygen from the chamber to interact with the product and vapors from the product to interact with the chamber environment. Also, gas-permeable materials exposed to hyperbaric oxygen will hold additional oxygen for some period of time after the exposure. These materials should be kept away from open flames for at least 20 minutes after the hyperbaric treatment.

Risk Assessment Process.

1. **Is there a more suitable alternative?**
   
   The issue of need must first be addressed. There may be a substitute dressing that has already been deemed acceptable for the hyperbaric environment. The wound dressing orders can be changed to the more desirable substitute (if there is no negative impact on patient outcome).
   
   It may be viable to remove the dressing before the hyperbaric treatment, leave it off during the treatment, and replace it after the treatment. Before making a decision, it is important to remember: some dressings should not be disturbed (e.g., a new skin graft), some dressings are designed to stay in place for several days, some dressings are very expensive, and it may be detrimental for the wound to remain undressed during the treatment.
   
   If there is a suitable alternative to using this dressing, the rest of the decision process can be eliminated.

2. **Does this dressing produce heat in the chamber?**
   
   Dressings are made from a large variety of materials. The concern is that materials in a dressing may rapidly oxidize and produce heat (exothermic reaction) when exposed to additional oxygen. For example, air-activated heat patches (commonly used for pain relief) have been tested in hyperbaric environments. The average operating temperature increased from 48.1°C (119°F) in normobaric air to 121.8°C (251°F) in hyperbaric oxygen. In this circumstance, the patient's skin would be burned and the heat could ignite combustible material in the chamber. If a material is isolated so oxygen cannot interact with it, an exothermic reaction will be prevented.
   
   Information on oxygen compatibility may be found in a product material safety data sheet (MSDS).

3. **Does this dressing produce too much static electricity?**
   
   All common textiles will contribute to static production. Wool and synthetic materials generally contribute more to static production than cotton. Although static charge is constantly accumulating, it will dissipate into the environment when humidity is present. At <30% relative humidity, static charge may accumulate faster than it can dissipate. At >60% relative humidity, static charge is all but completely eliminated.

   Use of conductive surfaces and electrical grounding will allow static charge to dissipate. Paragraph 20.2.7.4.1 requires all hyperbaric chambers to be grounded. Paragraph 20.2.9.1 requires any furniture installed inside a chamber to be grounded. Paragraph 20.3.1.5.3.2 requires all occupants of the chamber to be grounded when the oxygen percentage in the chamber is above 23.5 percent. The continuity of electrical grounds should be verified periodically.

4. **Does this dressing have a low ignition temperature/flash point?**
   
   In all hyperbaric environments, the partial pressure of oxygen is higher than at normal atmospheric conditions. Increasing the partial pressure of oxygen can change the classification of a material from non-flammable to flammable.
Many materials are flammable in a 100% oxygen environment.\textsuperscript{1} Any material used in a hyperbaric chamber should have an ignition temperature higher than the hottest thing it may contact. Paragraph 20.2.7.3.12 allows electrical equipment inside a class A (multiplace) chamber to reach a maximum temperature of 85°C (185°F). Paragraph 20.2.7.6.3 allows electrical circuits inside a class B (monoplace) chamber to reach a maximum temperature of 60°C (140°F). As the oxygen percentage increases, it takes less energy to ignite materials. This leads to more conservative decisions in a 100% oxygen environment. A greater margin of safety is achieved when there is a greater difference between the temperature limit (above) and the ignition temperature of material in question.

A material will release vapor into the chamber environment when it reaches its flash point temperature. Once a sufficient quantity of vapor is present in the chamber (LEL), it takes very little energy for ignition to occur. Paragraph 20.3.1.5.2.2 sets limits on flammable agents inside class A (multiplace) chambers. Paragraph 20.3.1.5.2.3 specifically prohibits flammable liquids, gases, and vapors inside class B (monoplace) chambers. If a material is isolated so that vapor cannot reach the chamber environment, it cannot contribute to the LEL. Information on ignition temperature and flash point may be found in a product MSDS.

5. Is the total fuel load too high?
If a fire does occur, the energy produced is a function of the partial pressure of oxygen and the total fuel load. In a hyperbaric environment, the partial pressure of oxygen is higher and contributes to greater energy production. Therefore, total fuel load inside the chamber should be minimized to only what is necessary. Any dressing product placed inside of a hyperbaric chamber is a combustible material and therefore adds to the fuel load.

6. Is there an adverse effect when this product is used inside the hyperbaric chamber?
It has been reported that the antibacterial agent Mafenide Acetate (Sulfamylon\textsuperscript{5}) in combination with hyperbaric oxygen has a poorer clinical result than either one by itself.\textsuperscript{5} There may be other drug interactions with hyperbaric oxygen that are undesirable.

The mechanical effects of pressure change may cause a dressing material to rupture. If the material is capable of venting/equalizing during pressure change, this should not occur.

7. Documentation.
The hyperbaric facility should maintain a "go list" and a "no-go list" of items that have been evaluated for hyperbaric use. In addition to this list, it is important to keep documentation on file explaining the risk assessment for each item. This will prevent future duplication of effort. It also serves as evidence that due-diligence was performed.

References.

****Insert Artwork Here****

**Substantiation:** Paragraph 20.3.1.5.4.3 allows a physician and safety director to use wound dressing products that are otherwise prohibited by the standard. There is no guidance in the standard on how to decide if the exception is prudent. The proposed annex text offers guidance on how to make this decision.

**Committee Meeting Action:** Accept in Principle

Revise the proposed language as follows:

\texttt{(A.20.3.1.5.4.3 (New))}

Risk Assessment Process for Hyperbaric Wound Dressings and Textiles

**Definitions\textsuperscript{1}**

Combustion: A chemical process of oxidation that occurs at a rate fast enough to produce heat in the form of either a glow or a flame.

Flammable: A combustible (solid, liquid, or gas) that is capable of easily being ignited and rapidly consumed by fire. Flash Point: The minimum temperature of a liquid or solid at which it gives off vapor sufficient to form an ignitable mixture with oxygen under specified environmental conditions.

Ignition Temperature: The minimum temperature required to initiate or cause self-sustaining combustion under specified environmental conditions.

Lower Explosive Limit (LEL) or Lower Flammable Limit (LFL): The minimum concentration of fuel vapor (% by volume)
over which combustion will occur on contact with an ignition source.

General Information

This risk assessment process was designed to evaluate wound dressing products for use in a hyperbaric chamber. However, the same decision process can be applied to the evaluation of textiles for hyperbaric use.

Wound dressings are commonly used inside hyperbaric chambers. They play an important role in infection control and patient outcome. Important safety concerns include: production of heat, production of static electricity, production of flammable vapor, ignition temperature, and total fuel load.

Many wound dressings employ fabrics and other materials that are gas-permeable. It is a common misconception that a gauze bandage will isolate an undesirable product from the chamber environment. Gauze is gas-permeable and will allow oxygen from the chamber to interact with the product and vapors from the product to interact with the chamber environment. Also, gas-permeable materials exposed to hyperbaric oxygen will hold additional oxygen for some period of time after the exposure. These materials should be kept away from open flames for at least 20 minutes after the hyperbaric treatment.1

Risk Assessment Process

**** Insert Artwork Here ****

1. Is there a more suitable alternative?
The issue of need must first be addressed. There may be a substitute dressing that has already been deemed acceptable for the hyperbaric environment. The wound dressing orders can be changed to the more desirable substitute (if there is no negative impact on patient outcome).

It may be viable to remove the dressing before the hyperbaric treatment, leave it off during the treatment, and replace it after the treatment. Before making this decision, it is important to remember: some dressings should not be disturbed (e.g. a new skin graft), some dressings are designed to stay in place for several days, some dressings are very expensive, and it may be detrimental for the wound to remain undressed during the treatment.

If there is a suitable alternative to using this dressing, the rest of the decision process can be eliminated.

2. Does this dressing produce heat in the chamber?
Dressings are made from a large variety of materials. The concern is that materials in a dressing may rapidly oxidize and produce heat (exothermic reaction) when exposed to additional oxygen. For example, air-activated heat patches (commonly used for pain relief) have been tested in hyperbaric environments. The average operating temperature increased from 48.1°C (119°F) in normobaric air to 121.8°C (255°F) in hyperbaric oxygen.3 In this circumstance, the patient’s skin would be burned and the heat could ignite combustible material in the chamber.

Information on oxygen compatibility may be found in a product material safety data sheet (MSDS).

3. Does this dressing produce too much static electricity?
All common textiles will contribute to static production. Wool and synthetic materials generally contribute more to static production than cotton. Although static charge is constantly accumulating, it will dissipate into the environment when humidity is present. At <30% relative humidity, static charge may accumulate faster than it can dissipate. At >60% relative humidity, static charge is all but completely eliminated.4

Use of conductive surfaces and electrical grounding will allow static charge to dissipate. Paragraph 20.2.7.4.1 requires all hyperbaric chambers to be grounded. Paragraph 20.2.9.1 requires any furniture installed inside a chamber to be grounded. Paragraph 20.3.1.5.3.2 requires all occupants of the chamber to be grounded when the oxygen percentage in the chamber is above 23.5%. The continuity of electrical grounds should be verified periodically.

4. Does this dressing have a low ignition temperature/flash point?
In all hyperbaric environments, the partial pressure of oxygen is higher than at normal atmospheric conditions. Increasing the partial pressure of oxygen can change the classification of a material from non-flammable to flammable. Many materials are flammable in a 100% oxygen environment.1

Any material used in a hyperbaric chamber should have an ignition temperature higher than it may be exposed to. Paragraph 20.2.7.3.12 allows electrical equipment inside a class A (multiplace) chamber to reach a maximum temperature of 85°C (185°F). Paragraph 20.2.7.6.3 allows electrical circuits inside a class B (monoplace) chamber to reach a maximum temperature of 60°C (140°F). As the oxygen percentage increases, it takes less energy to ignite materials. This leads to more conservative decisions in a 100% oxygen environment. A greater margin of safety is achieved when there is a greater difference between the temperature limit (above) and the ignition temperature of material in question.

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A material will release vapor into the chamber environment as it approaches its flash point temperature. Once a sufficient quantity of vapor is present in the chamber (LEL), it takes very little energy for ignition to occur. Paragraph 20.3.1.5.2.2 sets limits on flammable agents inside class A (multiplace) chambers. Paragraph 20.3.1.5.2.3 specifically prohibits flammable liquids, gases, and vapors inside class B (monoplace) chambers.

Information on ignition temperature and flash point in air may be found in a product MSDS.

5. Is the total fuel load too high?
If a fire does occur, the energy produced is a function of the partial pressure of oxygen and the total fuel load. In a hyperbaric environment, the partial pressure of oxygen is higher and contributes to greater energy production. Any dressing product placed inside of a hyperbaric chamber is a combustible material and therefore adds to the fuel load. Therefore, total fuel load inside the chamber should be minimized to only what is necessary.

6. Is there an adverse effect when this product is used inside the hyperbaric chamber?
It has been reported that the antibacterial agent Mafenide Acetate (Sulfamylon®) in combination with hyperbaric oxygen has a poorer clinical result than either one by itself. There may be other drug interactions with hyperbaric oxygen that are undesirable.

The mechanical effects of pressure change may cause a dressing material to rupture. If the material is capable of venting/equalizing during pressure change, this should not occur.

7. Documentation
The hyperbaric facility should maintain a “use list” and a “do not use list” of items that have been evaluated for hyperbaric use. In addition to this list, it is important to keep documentation on file explaining the risk assessment for each item. This will prevent future duplication of effort. It also serves as evidence that due-diligence was performed.

References

Committee Statement: The revised wording incorporates references to other standards and articles. See A.14.3.1.5.4.3 in the preprint.

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99-533 Log #CP117 HEA-HYP (C.20) Final Action: Accept

Submitter: Technical Committee on Hyperbaric and Hypobaric Facilities,
Recommendation: Move all of Annex C.20 to new Annex B.
Substantiation: The material found in annex C.20 is valuable and needs to be retained.
Committee Meeting Action: Accept
Committee Statement: Appears in the preprint in B.14.

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Risk Assessment Process for Hyperbaric Wound Dressings

1. More suitable alternative?
   - YES: ADD TO NO-GO LIST
   - NO

2. Produces heat?
   - YES: Can it be isolated?
     - NO: ADD TO NO-GO LIST
   - NO

3. Produces gas?
   - YES: Can it be grounded?
     - NO: ADD TO NO-GO LIST
   - NO

4. Low flash point?
   - YES: Can it be isolated?
     - NO: ADD TO NO-GO LIST
   - NO

5. Too much fun?
   - YES: Can you emit gas?
     - NO: ADD TO NO-GO LIST
   - NO

6. Adverse effect?
   - YES: ADD TO NO-GO LIST
   - NO

7. Document

ADD TO GO LIST
PRODUCT

1. More suitable alternative? → YES ADD TO USE LIST
   NO

2. Produce heat? → YES ADD TO USE LIST
   NO

3. Produce static? → YES Can it be grounded? → NO ADD TO USE LIST
   NO

4. Low flash point? → YES ADD TO USE LIST
   NO

5. Too much fuel? → YES Can you limit quantity? → NO ADD TO USE LIST
   NO

6. Adverse effect? → YES ADD TO USE LIST
   NO

7. Document

ADD TO USE LIST

Figure 20.3.1.5.4.3 (Log #231 CA)
C.20.1.1.3.1 Materials that might not ignite in air at atmospheric pressure or require relatively high temperatures for their ignition but that burn vigorously in 100 percent oxygen include, but are not necessarily limited to, the following: tricresyl phosphate (lubricant); certain types of flame-resistant fabrics meeting the flame propagation performance criteria of NFPA 701; silicone rubber; polyvinyl chloride; asbestos-containing paint; glass fiber-sheathed silicone rubber-insulated wire; polyvinyl chloride-insulated asbestos-covered wire and sheet; polyamides; epoxy compounds; and certain asbestos blankets.

Note that flammable lubricants are used widely in equipment designed for conventional use, including shafts, gear boxes, pulleys and casters, and threaded joints, which are coupled and uncoupled.

Substantiation: NFPA 701 is a test for fabrics and lightweight materials (textiles and films). It is appropriate to use NFPA 701 in this instance, but the correct terminology should be used. Moreover, there is no “small-scale test” in NFPA 701. The test to be used will be a function of the weight per unit area of the fabric to be tested.

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 in Principle

Revise to read as follows:

Materials that might not ignite in air at atmospheric pressure or require relatively high temperatures for their ignition but that burn vigorously in 100 percent oxygen include, but are not necessarily limited to, the following: tricresyl phosphate (lubricant); certain types of improved fire performance flame-resistant fabrics; silicone rubber; polyvinyl chloride; asbestos-containing paint; glass fiber-sheathed silicone rubber-insulated wire; polyvinyl chloride insulated asbestos-covered wire and sheet; polyamides; epoxy compounds; and certain asbestos blankets.

Note that flammable lubricants are used widely in equipment designed for conventional use, including shafts, gear boxes, pulleys and casters, and threaded joints, which are coupled and uncoupled.

Committee Statement: The term flame resistant was deleted and this information was moved to new annex B.14.