May 6, 2024

RE: Appeal, Soft-sided Hyperbaric Chamber Use

CITY OF DES MOINES
FIRE DEPARTMENT

Dear Board Members,

There is an appeal to the Des Moines Fire Department's (DMFD) decision on prohibiting the use of hyperbaric chambers that do not comply with ASME-PVHO within commercial buildings.

The International Fire Code (IFC) requires that NFPA 99, Health Care Facilities Code (NFPA 99) be followed for hyperbaric facilities which requires ASME-PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy (ASME-PVHO-1) for the construction standard of hyperbaric chambers. No documentation or other information could be provided to indicate that the soft-sided hyperbaric chamber in question meets or has obtained the ASME-PVHO-1 compliance. Since this equipment is within the scope of the IFC and NFPA 99, but does not meet ASME-PVHO-1 as required by NFPA 99, DMFD issued a stop work order for the soft-sided chamber and required that it be removed from the building.

The appellant, Dr. LoRang, requested DMFD to visit his business to ensure that he was compliant with fire code. At the time of the initial visit there were two chambers present. One of them was a hard-sided chamber which has a metallic placard indicating ASME-PVHO-1 compliance and was supplied directly from oxygen tanks, which after some additional work was found to be acceptable. The other chamber was a soft-sided chamber with its own oxygen concentrator device as a supply. The soft-sided chamber was not clearly compliant with NFPA 99 or ASME-PVHO-1 and after providing time for procuring documentation DMFD required that the soft-sided chamber no longer be used and eventually DMFD required it to be removed from the building.

At the time of many of the discussions with the appellant DMFD enforced the 2018 IFC, but the city has since adopted the 2021 IFC. No significant changes are apparent regarding this topic of hyperbaric chambers. This document will refer to the 2021 IFC.

IFC (2021 edition):

SECTION 609
HYPERBARIC FACILITIES

609.1 General. Hyperbaric facilities shall be inspected, tested and maintained in accordance with NFPA 99.

609.2 Records. Records shall be maintained of all testing and repair conducted on the hyperbaric chamber and associated devices and equipment. Records shall be available to the *fire code official*.

IFC indicates that it references the 2021 edition of NFPA 99 in Chapter 80:

99—21: Health Care Facilities Code

NFPA 99 (2021 edition):

1.1.12* Hyperbaric Facilities. Chapter 14 establishes criteria for design and operation of hyperbaric chambers and facilities. Chapter 14 covers electrical, fire, pressure, and gas hazards associated with hyperbaric facilities that are used, or intended to be used, for medical and experimental procedures at gauge pressures from 0 kPa to 690 kPa (0 psi to 100 psi).

14.2.2 Fabrication of the Hyperbaric Chamber.

14.2.2.1* Chambers for human occupancy and their supporting systems shall be designed and fabricated to meet ASME PVHO-1, *Safety Standard for Pressure Vessels for Human Occupancy*, by personnel qualified to fabricate vessels under such codes.

14.2.2.2 The chamber shall be stamped in accordance with ASME PVHO-1, *Safety Standard for Pressure Vessels for Human Occupancy*.

NFPA 99 Proposed TIA No. 1735 was submitted for review last summer which is very similar to this appeal. The proposal was to essentially make an exemption in the standard for soft-side chambers by recategorizing them and not holding them to the same requirements as other chambers. The committee vote on this proposal was:

1 – Abstained (The committee chair only wanted to vote in the event of a tie)
0 – Agree
17 – Against

The entire TIA proposal and committee comments can be viewed at the following link:
https://docinfofiles.nfpa.org/files/AboutTheCodes/99/99_2024_HEA_HYP_Log1735_tiaballot_final.pdf

Some excerpts from this document (highlighting added to help clarify):

Robert B. Sheffield

In the TIA substantiation, the assertion that "hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations" is not correct. All pressure vessels for human occupancy capable of 2psi or greater fall under ASME-PVHO-1. In NFPA 99, Chapter 14 applies to any chamber used at 0psi-100psi. Existing NFPA 99, Chapter 14 requirements for Category 3 hyperbaric care apply to installations with mild hyperbaric chambers.

James Edwin Bell

History: This proposal was first submitted as Public Comment No 103-NFPA 99 2022 (section 14.1.3.4) with a related item FR997. The committee rejected but held for the next cycle. The proposed revision is new material and needs to be held for the next revision cycle to allow for public review in accordance with 4.4.4.2 and 4.4.8.3 of the Regulations Governing the Development of NFPA Standards. The noted FR-997 does not address the concept of mild hyperbaric therapy and is not related to the new material. The proposed definition of a Category 4 in chapter 14 looks to me like the existing definition of Category 3 in Chapter 4. Currently there is a related CAM 99-47 to be debated June 22 at the technical session. This TIA #1735 is the same issue, a proposal for a change to 99 chapter 14 to add a category 4. Response: The submission contains multiple errors, incorrect statements, and questionable logic. 1. ASME has not changed the scope regarding pressure vessels for human occupancy (PVHO). The scope of ASME PVHO-1 is for any pressure vessel that encloses a human within the pressure boundary while under internal or external pressure exceeding a differential pressure of 2 to 100 psi. The only exclusions in ASME PVHO-1 I am aware of are for; nuclear reactor containments, pressurized airplane cabins, areospace vehicle cabins, and caissons. There is a procedure for non standard designs to use to meet ASME PVHO-1 called a code case. There is at least one other manufacturer of a non metallic chamber that has used a code case to meet ASME PVHO-1 rules. 2. NFPA 99 chapters 1.1.12, 3.3.80, and the Undersea and Hyperbaric Medical Society (UHMS) definition of hyperbaric oxygen therapy, were used to support the idea that the Restore Hyper Wellness locations are not hyperbaric facilities, therefore NFPA 99, chapter 14 does not apply. In my opinion this is incorrect. NFPA 99 1.1.12 defines criteria for design, operation and hazards for hyperbaric chambers and facilities that are intended for use at pressures 0-100 psig. NFPA 99 3.3.80 defines Hyperbaric facilities as locations housing chambers and service equipment for chambers used at pressures above atmospheric pressure. The UHMS is not an enforcement or code agency, and the definition of a hyperbaric treatment varies widely worldwide. It is not the HEA/HYP technical committees' role to determine treatment pressures. That is a medical decision. It is our role to recognize and mitigate the hazards. The chambers in the submission are intended for use within the pressure range of NFPA 99 for hyperbaric chambers and are subject to the same rules as any other hyperbaric chamber and facility housing the chamber. 3. The documents submitted state that the space for the Restore Hyper Wellness is classified as a business occupancy. NFPA 101 requires any occupancy containing a hyperbaric chamber to comply with NFPA 99. NFPA 101 8.7.5* Hyperbaric Facilities, 18.3.2.3 Hyperbaric Chambers, and 19.3.2.3 Hyperbaric Chambers, ..."all occupancies shall comply with NFPA 99"... 4. NFPA 99 chapter 14 requires that hyperbaric chambers be fabricated to ASME PVHO-1, housed, maintained, and operated per the provisions of the chapter. 5. The documentation included for review cites an FDA 510k and includes oxygen % testing from the chamber atmosphere. The FDA 510k issued for these types of chambers is for the treatment of acute mountain sickness with air. The models demonstrated in the submission are not cleared by the FDA for any other treatment, or for oxygen use. https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts. From the testing data submitted, supplemental O2 by mask is used in addition to the pressurization air for these chambers.

Francois Burman	There are multiple anomalies, false assertions, and unsafe implications in this new item and associated modifications to the code, which was not discussed during any of the committee meetings. It has not passed the same scrutiny that any other public inputs are required to undergo. As such, I am not able to agree to it. At the very least: 1. Proposed 14.1.3.4 (3) conflicts with 14.4.3. The former limits pressure to 5 psi; the later addresses decompression from 29 psi. 2. 14.4.2.1 reduces the ventilation rate to one far too low to prevent CO2 build-up or flushing out any elevated levels of oxygen. The minimum safe limit is 64 lpm per person (as per a published industry document), determined for an air-filled chamber. 3. A14.4.3 - emergency egress. An expert medical opinion has been published that states that rapid depressurization from as little as 2 psi can cause harm. 5 psi is much higher than this and is likely to cause significant barotrauma. 4. Substantiation: (a) There is no gap in the NFPA 99 code for any compliant chamber. This substantiation seeks to allow an exemption for a specific type of product. As the stated pressure is 5 psi, such a chamber should comply with both NFPA and ASME PVHO-1 as currently published. (b). The substantiation that the ASME PVHO-1 committee has in anyway stated that soft-sided mild hyperbaric chambers do not fall under the purview of ASME PVHO-1 is untrue. All chambers above 2 psi are covered. There is no identifiable gap for any chamber above 2 psi in ASME PVHO-1. Oxygen administration is not a factor in this deliberation. The SOS Hyperlite is one of the soft-sided chambers that are covered under ASME PVHO-1 as it meets all the published requirements in the code and associated code case. There are others too. I serve on the ASME PVHO-1 and -2 committees. I would like to see where we made any such statements. (c) ASME PVHO-1 is not limited to 'high pressure' but to any pressure above 2 psi (differential). (d) These chambers are covered under existing category 3 in NFPA 99 Chpt 14. (d) There is no emergency nature to this application. The safeguards to patients, staff and to the public are in place. Adopting this change would in fact have the opposite effect and introduce a clear risk to chamber occupants at the very least.
Deepak Talati	I have listed my response below based on my technical knowledge and experience. 1. The substantiation of TIA states, "...mild-pressure do not fall under the purview of ASME-PVHO regulations....". This is an incorrect statement. The proposed section 14.1.3.4 (c) states the chamber gauge pressure is less than 34.5 KPa (5 psi). PVHO-1 section 1-2.1 states "This standard applies to all pressure vessels that enclose a human within their pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi (15KPa)." Since the differential pressure can be more than 2 psi, PVHO does apply. 2. The proposed section 14.4.1.2 states that the chamber shall be classified as a Class B chamber. Section 14.1.2.2 (2) of the current code states Class B as a Human, occupancy and there are applicable sections 14.2 & 14.3. This new proposal is requesting to create another set of requirements for the same Class B chambers. This will make it difficult to enforce the code. If required, a new classification should be created. 3. The proposed section 14.4.3 discusses the requirement for emergency depressurization. This emergency depressurization requirement is for chambers with maximum operating pressure of 3 ATA. Since the maximum operating pressure of the proposed chambers is 5 psi, there should be specific requirements for these chambers. 4. No requirements for the quality of the compression gas are specified. The report (Page 5 of 8) states that the air from the compressors be sampled every (6) months to ensure that the air being supplied to the chambers is safe. How do you determine if the air is safe if no standard is mentioned?
Anthony L. Johnston	Given that PVHO-1 covers any pressure vessel 2 psi or higher, regardless of oxygen concentration, this proposal provides false evidence claiming a contradiction between ASME-PVHO and NFPA. PVHO-1 is an applicable reference as noted in NFPA 99 2.3.4 The evidence includes the statement "Moreover, the addition of an oxygen concentrator does not increase the risk of combustion, nor does it pose any danger to the patient or attendant" which implies there will be an increased oxygen environment. The claim the device itself should be exempted purely because it is not manufactured to operate with oxygen does not excuse its intended use from the code where increased oxygen concentration is an integral function. The evidence claim that chambers compressed to higher than 2 psi gauge are not considered "hyperbaric facility" per NFPA 99 3.3.80 is false as the reason "that Restore Hyper Wellness locations are not using the chambers to provide hyperbaric medical treatment to occupants" is blatantly false when compared with the company's advertising to "enhance your body's natural healing processes" where one may "optimize sleep, speed up athletic recovery, repair muscles and boost cognitive clarity," which are clearly medical claims of efficacy. The use of UHMS definition to avoid NFPA 99 applicability is inappropriate given ASME PVHO-1 citation in NFPA 99 2.3.4 & NFPA 99 14.2.1.4.3 & 14.2.1.5.3. The UHMS is not a recognized source for NFPA code. The evidence does not support exemption from NFPA 99 due to the intended use of concentrated oxygen in its operating capacity (page 7 & 20 of provided evidence). Additionally, requirements for compressed air under NFPA 14.2.4.2 would inherently apply under all operating conditions.
Ramesh K. Dixit	I don't agree with the incorrect substantiation provided by the proposal submitter that "there is an identifiable gap now that ASME has stated hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations as these models are not operating with high pressure and 100% medical oxygen administration.....". Being an active current member of ASME-PVHO standards committee, I am not aware of such statements or publications by ASME PVHO committee. Section 1-2.1 of PVHO-1-2019 states that "This Standard applies to all pressure vessels that enclose a human within their pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi (15 kPa)....." In my professional opinion, 5 psi internal working pressure, human rated, soft-shell chambers clearly fall in the prevue of ASME PVHO-1. Since these chambers are being constructed from non-standard and flexible materials, ASME PVHO-1 appendix E provides a clear guidance about preparing a Code Case for submission to ASME PVHO Committee for review and approval. At least one of the flexible chamber manufacturers has done that in the past and obtained PVHO-1 compliance for their chamber. So, procedures and pathway for development of such chambers already exist currently published PVHO-1. Hyperbaric Facilities definition (section 1.1.12) of NFPA 99-2021 states that Chapter 14 establishes criteria for design and operation of hyperbaric chambers and facilities. Chapter 14 covers electrical, fire, pressure, and gas hazards associated with hyperbaric facilities that are used, or intended to be used at gauge pressures from 0 psi to 100 psi. Furthermore, TIA does not list any requirements for air compressor piping, active sample monitoring or quality of the air to be used for chamber pressurization. In my opinion, it must meet the requirements of Category 3 Air Quality Requirements described in Chapter 5 of NFPA 99-2021 (Section 5.3, Category 3 Piped Gas and Vacuum Systems).
Jeff Mize	The assertion made in the TIA substantiation regarding the exclusion of mild-pressure hyperbaric chambers from ASME-PVHO regulations is inaccurate. Proposed Section 14.1.3.4 conflicts with the existing 14.1.3.3, which addresses risk classifications. According to 14.1.3.3 and other sections of NFPA 99, systems where failure is deemed "not likely" to cause harm to patients, staff, and visitors are classified as Category 3. ASME-PVHO-1 mandates that all pressure vessels designed for human occupancy and capable of sustaining pressures of 2 psi or higher must adhere to these regulations. Moreover, NFPA 99, Chapter 14 applies to any chamber operating within the pressure range of 0 psi to 100 psi. The current requirements specified in NFPA 99, Chapter 14 specifically apply to Category 3 hyperbaric care and are relevant to installations incorporating mild hyperbaric chambers.

As the proposal was denied, the 2024 edition of NFPA 99 still requires all hyperbaric chambers to comply with ASME-PVHO-1, and the committee members comments clearly indicate that soft-wall chambers are meant to be within the scope of and regulated by NFPA 99.

The FDA approval of this device was provided as an attempt at an alternative to ASME-PVHO-1, however without information comparing the scope of these standards and the passing criteria of each I am unable to confirm that the FDA approval is equivalent in terms of fire safety. As noted in the comments above in the proposed TIA comments, the FDA has issued a clarification document at this link: https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts
Below is a snapshot from this FDA webpage indicating that the FDA approval of these devices are not intended to include use with supplemental oxygen:

Other hyperbaric devices

The FDA has also cleared a large, zippered bag that is intended to treat altitude sickness only.

These zippered chambers for treating altitude sickness provide pressure but do not attach to oxygen tanks. The FDA has not cleared these bags for use with oxygen tanks or oxygen concentrators. However, the FDA is aware of instances in which people used these bags to create homemade HBOT devices, which can pose the risk of fire and suffocation.

The introduction of concentrated oxygen into a space with the potential to create an oxygen enriched environment creates a significant fire hazard. Atmospheric concentrations of oxygen are normally 20.95%. OSHA 1910.146(b) defines an atmospheric oxygen concentration above 23.5% as a hazardous atmosphere. NFPA 99 also points to an oxygen concentration of 23.5% in the definition of an Oxygen-Enriched Atmosphere. Items that are flammable will burn hotter, faster and are easier to ignite with higher oxygen availability and items that that do not burn at all at normal atmospheric levels of oxygen can become flammable in oxygen enriched environments. Something as simple as a spark from static electricity can be sufficient to start a fire.

In summary DMFD has taken no stance on medical safety, its FDA compliance or efficacy of these hyperbaric chambers. DMFD is only reviewing compliance for them to safely be used within a commercial building. The soft-sided hyperbaric chamber in question is desired to be used with supplemental oxygen and is covered by the fire codes mentioned. Further, the FDA approval does not have adequate supporting documentation to deem it as an equivalent or alternative to ASME-PVHO-1 and there is no indication that obtaining this documentation would support this argument. The NFPA 99 committee should be viewed as the non-biased subject matter experts, and they have specifically addressed this topic in their denial of the request to loosen the requirements around these devices.

It is recommended that the board vote to deny the appeal request for allowing the use of the non-compliant soft-sided chamber within the commercial building.

Sincerely,

Jeremy Eekhoff, Fire Protection Engineer
Fire Prevention Bureau
Des Moines Fire Department