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M E M O R A N D U M

TO: Technical Committee on Hyperbaric and Hypobaric Facilities

FROM: Elena Liolin, *Senior Committee Administrator*

DATE: July 21, 2023

SUBJECT: NFPA 99 Proposed TIA No. 1735 **FINAL TC BALLOT RESULTS**

The public comment circulation has passed, therefore, according to Section 5.7(a) in the NFPA *Regs*, the final results show this TIA **HAS NOT** achieved the ¾ majority vote needed on both Ballot Item No. 1 (**Technical Merit**) and Ballot Item No. 2 (**Emergency Nature**).

20 **Eligible to Vote**
2 **Not Returned** *(Chiffoleau, Ramos)*

Technical Merit:

1 Abstention *(Puchovsky)*
0 Agree
17 Disagree *(Beal, Bell, Bryant, Burman, Charash, Cone, Dixit, Garay, Garrett, Gresho, Gustavson, Hummel, Johnston, Mejia, Mize, Sheffield, Talati)*

Emergency Nature:

1 Abstention *(Puchovsky)*
0 Agree
17 Disagree *(Beal, Bell, Bryant, Burman, Charash, Cone, Dixit, Garay, Garrett, Gresho, Gustavson, Hummel, Johnston, Mejia, Mize, Sheffield, Talati)*

There are two criteria necessary to pass ballot [(1) simple majority (2) affirmative ¾ vote]. Both questions must pass ballot in order to recommend that the Standards Council issue this TIA.

(1) In all cases, an affirmative vote of at least a simple majority of the total membership eligible to vote is required.
[20 eligible ÷ 2 = 10 + 1 = **(11)**]

(2) The number of affirmative votes needed to satisfy the ¾ requirement is **13.**
(20 eligible to vote - 2 not returned - 1 abstentions = 17 × 0.75 = 12.75)

Ballot comments are attached for your review.

The *Regs* at Section 1.6.2.(c) state: An appeal relating to a proposed Tentative Interim Amendment that has been submitted for processing pursuant to Section 5.2 shall be filed no later than 5 days after the notice of the TIA final ballot results are published in accordance with Section 4.2.6.

Appeal Closing Date for this TIA is **July 26, 2023.**

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

QUESTION NO. 1: I AGREE with the TECHNICAL MERITS of the Proposed TIA Log No. 1735 to revise paragraphs 14.1.3.4, 14.1.4, and add a new section 14.4.

Eligible to Vote: 20
Not Returned : 2
Gwenael Chiffoleau,Coleen Ramos

Vote Selection	Votes	Comments
AGREE	0	
DISAGREE	17	
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.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

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.
W. Robert Bryant	There are many soft chambers located in Doctors Offices which are being used with oxygen levels in the 95-97% range to treat disorders that are approved for payment by Medicare and at pressures that require compliance with ASME PVHO 1

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

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.
Martin T. Gresho	No code gap exists. 1. Soft sided chambers are currently within the scope of CH14 and are conservatively addressed. 2. It is unclear how the letter from the Industrial Hyperbarics Association provided as substantiation, which appears to be a record of conversation with a single individual, can exempt soft shell chambers from any ASME code that includes them. A clear exemption from ASME code in the ASME code is warranted. This needs to be better explained. The proposed new text does not require fire sprinklers and the existing code does. No explanation for this reduction in fire safety is offered. This topic is addressed in a "Reject but hold" public comment from the 2nd draft meeting and will be addressed as a public input during the next 1st draft meeting. This is appropriate. No TIA is warranted.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

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?
David Lindsie Cone	There are a number of safety concerns with improper application of these devices that were not properly addressed within the document. Changes in pressure of only 80mmHg are adequate to result in pulmonary barotrauma and subsequent cerebral arterial gas embolism. Older patients and those with co-morbidities are at significantly greater risk for issues in these chambers to include egress in the case of emergency.
Adrian Garay	Section 14.1.3.4 as proposed for category 4 hyperbaric care fails to indicate what category of gas piping system or electrical service system shall be followed for safe and effective care. By not addressing the category of gas piping and category electrical service it presents a hazard to life if not addressed. 14.1.4 as proposed adds a hazard to life if 14.2 and 14.3 are not applicable.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

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.
David Charash	The safety of the device requires an independent safety evaluation as it it a device that is used to offer treatment to patients (humans).
Leah Hummel	Proposed Section 14.1.3.4 is in conflict with existing 14.1.3.3 regarding risk classifications. In 14.1.3.3 as well as elsewhere is NFPA 99, systems in which failure is "not likely" to cause injury to patients, staff, and visitors are Classified as Category 3. I do not have enough information at this time to determine whether the additional text of "less than 5psi pressure" and "oxygen concentration of less than 25%" is appropriate for Category 4 classification. What are the risk factors that cause this to be "not likely" versus "no impact?" I feel the committee needs to discuss these risk factors before I feel comfortable voting "agree."
Derall Garrett	As a committee member, I have observed that we usually discuss proposed changes in public comments. However, the current suggestions have not been thoroughly examined yet. I am concerned that rushing to incorporate these changes in the 2024 edition could compromise safety measures. In my opinion, implementing these changes without detailed discussion could result in a higher risk for everyone involved. Therefore, I cannot support these suggestions until the committee can review and discuss them in more detail. The Proposed 14.1.3.4 (3) The proposal's section 14.4 states that pressure should be kept below 5 psi. However, this conflicts with the proposed section 14.4.3, which mentions an emergency decompression form for 3ATA that requires a much higher pressure. 14.1.4.2 –Sections 41.2 and 14.3 are not applicable. Any facility that houses a hyperbaric chamber must adhere to specific code standards and regulations. 14.4.2.1 The ventilation rate is insufficient to prevent the accumulation of CO2. Additionally, many of these units lack gas monitors, making it impossible to determine the composition of the chamber environment. 14.4.3, A14.4.3 – Arterial gas embolism can occur at pressures as low as 2 psi, and at 5 psi it can cause significant damage to both the lungs and ears. Based on my experience, patients have reported experiencing ear pain even at pressures as low as a quarter of a psi.
Andrew James Beal	Disagree. It is indeterminate to me if all statements regarding the technical merits are accurate.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

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).
Elmer Mejia		From my perspective, the current codes have effectively served their purpose in providing crucial guidance and ensuring safety for many years. Therefore, I do not see a pressing need to revise these paragraphs or introduce a new section, at this moment.
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.
Richard Bartlett Gustavson		The proposed changes will decrease safety standards in the hyperbaric community. I am not opposed to the concept but believe, based on personal experience, that introducing chambers that lower the safety standards is a mistake without additional discussion and modifications to assure the safety of the patients/clients.
ABSTAIN	1	
Milosh T. Puchovsky		As the newly appointed TC Chair I will abstain from vote on this matter unless my vote is needed to break a tie vote.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

QUESTION NO. 2: I AGREE that the subject is of an EMERGENCY NATURE for one or more of the reasons noted in the Instructions box.

Eligible to Vote: 20
Not Returned : 2
Gwenael Chiffoleau,Coleen Ramos

Vote Selection	Votes	Comments
AGREE	0	
DISAGREE	17	
Robert B. Sheffield		In the TIA, the assertion "As of today, there are no standards for the operation of soft-sided chambers within chapter 99." is incorrect. Safeguarding requirements already exist in NFPA 99, Chapter 14. The requirements for Category 3 hyperbaric care apply to installations with soft-sided or mild hyperbaric chambers. If the TIA is accepted, it would remove some of the safeguards.
James Edwin Bell		The substantiation states that... "ASME has created an identifiable gap in NFPA chapter 99"... Editorially, the language is incorrect regarding the NFPA chapter and does not identify the section of ASME. More importantly ASME has not changed the scope of ASME PVHO-1. The scope of ASME PVHO-1 applies to pressure vessels that enclose a human within the pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi(15kPa). There exists a clear path for non standard vessels to meet ASME PVHO-1 called a code case. There is at least one soft sided chamber manufacturer that has used a code case to obtain ASME PVHO-1 certification. In my opinion, there is no identifiable gap or emergency nature for a change to NFPA 99, chapter 14. There is no error or omission that was overlooked during the regular revision process. The submitter is encouraged to follow the due processes that already exist. The HEA/HYP technical committee and the public have not had the opportunity to review this proposal within the NFPA Standards Development process for new material. There are significant safety issues related to the fabrication, operation and maintenance of PVHOs. The normal due process should be followed, not these short notice and incomplete proposals. There have been injuries and fatalities from incidents with non certified chambers and / or certified chambers that were not fabricated, operated and maintained in accordance with NFPA 99 chapter 14.
W. Robert Bryant		I do not believe that any of the six suggested responses are applicable
Francois Burman		here 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.
Martin T. Gresho		No code gap exists. Soft side chambers are included in the scope of NFPA 99 Ch 14 currently and are treated the same as chambers with higher pressures and higher O2 concentrations. So a change in approach is warranted but no code gap exists.
Deepak Talati		I disagree that the subject is of an emergency nature. Discussion amongst committee members is necessary to address a lot of questions. This matter may be important and require attention but in my view it cannot be resolved with a TIA.
David Lindsie Cone		Due to the conditions for which patients will be treated with these low pressure devices and the general lack of therapeutic evidence and efficacy of "mild" hyperbaric oxygen therapy, this subject is not of an emergent nature.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

Adrian Garay	ASME-PVHO-1 as referenced in NFPA-99 section 14.2.2.1.1 is applicable to all pressure vessels that enclose a human within their pressure boundary while under internal pressure or external pressure exceeding a differential pressure of 2 psi. The design and fabrication of any chamber in accordance with ASME-PVHO-1 safety standard provides safety measures and reduces the risks of a hazard to life when complied with. Not complying with the safety standard increases the risk of hazards to life.
Anthony L. Johnston	There is no evidence this proposal corrects an adverse impact to the protection of property or life as a result of technical or safety justification. In contrast, this TIA proposal would reduce oversight of a known hazard where physical harm has been documented in as little as 1.7 psig (Hamilton-Farrell & Bhattacharyya, 2004). Hamilton-Farrell, M., & Bhattacharryya, A. (2004). Barotrauma. International Journal of the Care of the Injured, 35 (4), 359-370. https://doi.org/10.1016/j.injury.2003.08.020
David Charash	The testing that has been done to date is note done by an independent body and is subject to bias. The rational that mild hyperbaric chambers do not fall under the purview of ASME-PVHO not operating with high pressure/100% medical oxygen administration. As of today there are no standards of operation... This Is the reason that there is significant concern for the safe use this device Oxygen under even mild pressure even less than 100% increase the risk to the inhabitants. Another concern is the effect of the lower concentration of oxygen on the soft materials (non acrylic). There is no demonstration of the safety of this device for the application of its indication by an independent organization. Independent testing of each category of device related to the effect of higher concentrations of Oxygen on the soft material to determine if there is significant breakdown of the material leading to a potential fire hazard
Leah Hummel	By bringing this forward as a TIA and not running it through the normal revision process, the committee has not had sufficient opportunity to discuss the merits and disadvantages. I do not have enough information to vote "Agree," however I would consider voting for it during the normal process in the next revision cycle provided I had enough information.
Derall Garrett	This request aims to exempt a particular type of vessel that doesn't meet the safety standards set by the codes. It seeks to find a way to bypass these regulations. However, there are no gaps in the NFPA 99 code for compliant chambers. Changing the code only applies to chambers that don't meet the compliance requirements. A 5 psi chamber should comply with both NFPA and ASME PVHO-1, which are currently published.
Andrew James Beal	Disagree. It is indeterminate to me that this meets an emergency nature.

NFPA 99 (A2023) TIA Log No. 1735 - FINAL RESULTS

Ramesh K. Dixit		In my professional opinion, I believe there is no pressing emergency for development of Category 4 Hyperbaric Care at this time to cover the chambers proposed in TIA 1735. Rules for design, development, use of soft-shell chambers in a hyperbaric Facility setting are already covered adequately in currently published NFPA 99-2021 edition. I my expert opinion, these systems fall in the prevue of Category 3 systems as defined in section 4.1.3 of NFPA 99-2021. So, the statement asserted in TIA 1735 "As of today, there are no standards for the operation of soft-sided chambers within chapter 99." In my view is incorrect. Development of Category 4 section, if necessary, must follow the standard process of NFPA 99 Codes development so the proposal can be discussed in the committee meeting(s) and all design, development, fire and operational hazards can be adequately addressed and approved before publication.
Elmer Mejia		I respectfully suggest that rushing to handle this situation as an emergency may not be the most effective course of action. It is crucial to thoroughly examine and consider all pertinent technical details before arriving at a knowledgeable conclusion. While I value the insights provided so far, it is imperative to take the time needed to meticulously scrutinize all aspects in order to make the most informed and technical decision.
Jeff Mize		This application is not emergent in nature, as adequate safeguards are already in place to ensure the safety of patients, staff, and the general public. Implementing the proposed change would actually have a contrary outcome, introducing a discernible risk to individuals inside the chamber.
Richard Bartlett Gustavson		See my above comments. These chambers were introduced into the US years ago, ignoring the PVHO and NFPA safety criteria that were in place. They require additional discussion and consideration.
ABSTAIN	1	
Milosh T. Puchovsky		As the newly appointed TC Chair I will abstain from vote on this matter unless my vote is needed to break a tie vote.

NFPA 99-Proposed 2024 Edition
Health Care Facilities Code
TIA Log No.: 1735
Reference: 14.1.3.4, 14.1.4, 14.4 (new)
Comment Closing Date: July 13, 2023
Submitter: Hannah Jennewein, Restore Hyper Wellness
www.nfpa.org/99

1. Revise paragraph 14.1.3.4 to read as follows:

14.1.3.4 Category 4 Hyperbaric Care. ~~(Reserved)~~
Where all of the following conditions are met, the hyperbaric facility shall be considered Category 4 for use in this chapter:
(1) Interruption or failure of oxygen supply is not likely to cause injury to patients, staff, or visitors.
(2) Interruption or failure of electrical service is not likely to cause injury to patients, staff, or visitors.
(3) The chamber gauge pressure is less than 34.5 kPa (5 psi) and the oxygen concentration is less than 25 percent.

2. Revise paragraph 14.1.4 to read as follows:

14.1.4 Applicable Code. ~~Hyperbaric facilities that are conducting any form of treatment and are not located in a designated health care facility, including residential occupancies, shall comply with the requirements of the applicable code.~~
14.1.4.1 Hyperbaric facilities classified as Category 1, Category 2, or Category 3 that are conducting any form of treatment and are not located in a designated health care facility, including residential occupancies, shall comply with the requirements of the applicable code.
14.1.4.2 Hyperbaric facilities classified as Category 4 shall comply with the following requirements:
(1) Sections 14.2 and 14.3 shall not apply.
(2) The requirements of Section 14.4 shall apply.

3. Add a new section 14.4 to read as follows:

14.4 Category 4 Hyperbaric Facilities.
14.4.1 Construction and Equipment.
14.4.1.1 The facility shall be treated as a new facility.
14.4.1.2 The chamber shall be classified as a Class B chamber.
14.4.1.3 Chambers shall not be required to be protected by 2-hour fire-resistant-rated construction.
14.4.1.4 Where building exterior walls form part of the facility boundary, that portion of the facility boundary shall not require 2-hour fire-resistant-rated construction.
14.4.1.5 Service equipment shall be permitted to be located in multi-use spaces.
14.4.1.6 The supporting foundation for any chamber shall be designed to support the chamber.
14.4.1.7 The room housing the chamber shall contain a minimum of one 2-A:10B:C portable fire extinguisher.
14.4.2 Ventilation.
14.4.2.1 The minimum ventilation rate for the chamber shall be 0.0283 m^3/min (1 ft^3/min).

14.4.2.2 Where chambers are equipped with breathing apparatus, the breathing apparatus shall function at all pressures that can be encountered in the chamber.

14.4.3* Emergency Depressurization. Chambers shall be capable of depressurizing from 3 ATA (304.0 kPa absolute) to ambient pressure in not more than 2 minutes.

A.14.4.3 The mild hyperbaric oxygen therapy (mHBOT) chamber meets this requirement because the zippers can be forced open in the event of an emergency. The longer depressurization process is conducted in nonemergency situations for the comfort of the client.

14.4.4 Fire Protection.

14.4.4.1 Chambers shall not be required to comply with 14.2.6.

14.4.4.2 Signs prohibiting the introduction of flammable liquids, gases, and other articles not permitted by this chapter into the chamber shall be posted in the room housing the chamber(s).

14.4.4.3* A means for communication shall be provided within the room housing the chamber(s) for notifying the fire department.

A.14.4.4.3 The requirement from the fire protection and life safety analysis for a pull-station in the mHBOT chamber room satisfies this requirement.

14.4.4.4 If the building housing the hyperbaric facility has a central fire alarm system, the communication shall be a pull-station connected to the system.

14.4.5 Electrical Systems.

14.4.5.1 The requirements of *NFPA 70* or local electrical codes shall apply to electrical wiring and equipment in hyperbaric facilities within the scope of this chapter.

14.4.5.2 All hyperbaric chamber service equipment, switchboards, panels, or control consoles shall be located outside of, and in the vicinity of, the chamber.

14.4.5.3 For the fixed electrical installation, none of the following shall be permitted inside the chamber:

(1) Circuit breakers
(2) Line fuses
(3) Motor controllers
(4) Relays
(5) Transformers
(6) Ballasts
(7) Lighting panels
(8) Power panels

14.4.6 Administration and Maintenance.

14.4.6.1 This subsection contains requirements for administration and maintenance that shall be followed as an adjunct to physical precautions specified in Section 14.4.

14.4.6.2 Emergency procedures specific to the hyperbaric chamber shall be established.

14.4.6.3 All personnel shall be trained in emergency procedures.

14.4.6.4 Personnel shall be trained to control the chamber and decompress occupants when all powered equipment has been rendered inoperative.

Substantiation: This TIA request is to fill an identified gap in the safeguarding requirements that currently do not exist in a standard for soft sided mild hyperbaric chambers within NFPA Chapter 99. 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. As of today, there are no standards for the operation of soft-sided chambers. This gap in the code has prevented a large proportion of clients from accessing this potentially beneficial treatment. This change provides requirement to populate Category 4 and creates a new specific section for lower hazard chambers.

Emergency Nature: The proposed TIA intends to accomplish a recognition of an advance in the art of safeguarding property of life where an alternative method is not in current use or is unavailable to the public.

ASME has recently created an identifiable gap in the NFPA Chapter 99 code now that the organization 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. As of today, there are no standards for the operation of soft-sided chambers within chapter 99. It is urgent that the reserved section of Category 4 within chapter 99 is populated to create safeguarding requirements. Please see all uploaded documents for a detailed bases supporting the emergency nature of this TIA to require prompt action.

10719 Norwalk Blvd.
Santa Fe Springs, CA
90670
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March 15, 2023

To Whom this may Concern,

I am pleased to inform you that we have successfully tested the egress results for our Vitaeris 320 product, and we have achieved impressive results. We were able to achieve egress times under one minute for all five subjects who participated in the test.

Our team worked tirelessly to ensure that the Vitaeris 320 product meets the highest safety standards, and we are proud to share the results of our efforts with you. The egress times for each subject are as follows:

Subject 1: 45 seconds

Subject 2: 50 seconds

Subject 3: 55 seconds

Subject 4: 58 seconds

Subject 5: 59 seconds

We believe that these results demonstrate the exceptional quality of our product and its ability to ensure the safety of its users. We are confident that our customers will appreciate the level of safety and reliability that our Vitaeris 320 product provides.

If you have any questions or would like more information about our product, please do not hesitate to contact us. We are always happy to discuss our products and services with our valued customers.

Sincerely,

DocuSigned by:
Trevor Cetorelli
F550F71669F1439...

Trevor Cetorelli

Service and Sales Manager

April 17th, 2023

Hyperbaric chambers of soft-wall composition, that have been evaluated and granted an FDA 510 (k), are cleared for home and clinic use with an exceptional safety record. The soft-wall chamber models are designed to operate with a consistent air exchange (Flow-Through Method), ensuring no gas pooling. 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.

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. As of today, there are no standards for the manufacture and operation of soft-walled chambers. The International Hyperbaric Association (IHA) is working with the American Society of Mechanical Engineers (ASME) compiling research, industry participation and general interest in development of a standard for the soft walled chambers.

If you have any questions regarding soft walled chambers and are interested in participating, please contact IHA at the contact information provided below.

Shannon Kenitz
Executive Director IHA
skenitz@ihausa.org

Note: If you have any questions regarding ASME regulations please contact:

Thomas Costabile P.E.
Executive Director / CEO
ASME

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Hyperbaric Consulting LLC

"There's No Substitute For Experience!"

May 11, 2022

Restore Hyper Wellness
Corporate Headquarters
3601 S Congress Ave
Suite C-200
Austin, TX 78704

To Whom It May Concern:

You asked whether the Restore Hyper Wellness locations are required to comply with National Fire Protection Association ("NFPA") 99, Chapter 14. For the reasons set forth below, the answer is no – the Restore Hyper Wellness locations are not required to comply with NFPA 99, Chapter 14, because those locations do not contain a "hyperbaric facility" as defined in NFPA 99, Chapter 3.3.80. Therefore, NFPA 99, Chapter 14 does not apply to those locations. You also asked whether, assuming in the alternative that NFPA 99, Chapter 14 does apply to the Restore locations, such locations fall under Chapter 14.1.3.3, Category 3 Hyperbaric Care. For the reasons set forth below, the answer is yes – those locations would fall under Category 3 Hyperbaric Care, NFPA 99, Chapter 14.1.3.3, because the interruption or failure of electric power at the locations will not cause injury to occupants, staff, or visitors.

You also asked my opinion regarding how the Restore Hyper Wellness locations could reasonably reduce the risk of a fire occurring inside the chambers and therefore comply with the relevant provisions of NFPA 99, Chapter 14. Finally, you asked my opinion regarding how Restore Hyper Wellness locations could reasonably reduce the risk of an injury to an occupant if a fire were to occur outside the chambers and therefore comply with the relevant provisions of NFPA 99, Chapter 14. I provided recommendations below regarding those two issues.

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"There's No Substitute For Experience!"

CREDENTIALS AND BACKGROUND

In 1986, I obtained an Emergency Medical Services degree (Paramedic) from Miami Dade Medical College. That same year, I obtained a Fire Science Degree (Firefighter) from the Broward Fire Academy.

I am the owner of HYPERBARIC CONSULTING LLC, where we provide hyperbaric care consulting services to hospitals, clinics, chamber manufacturers, physicians, and other medical professionals. We have been in business for over eight (8) years. I am also a Hyperbaric Clinical Specialist for Perry Baromedical and have held that position for approximately seven (7) years. I am also a Hyperbaric Facility Surveyor for the Undersea and Hyperbaric Medical Society ("UHMS") and have held that position for approximately eighteen (18) years.
I previously served as a Member of the International Board of Undersea Medicine for approximately five (5) years. I also previously served as Vice President of Hyperbaric Services for Comprehensive Healthcare for approximately nine (9) years.
I am also a Member of the NFPA 99 Technical Committee on Hyperbaric and Hypobaric Facilities and have held that position for approximately fourteen (14) years. As a Voting Member of the NFPA 99 Technical Committee, part of my responsibilities is to review proposed code language for future editions.

I am also a Specialist for the Reserve Responder Program at the Hillsborough County Fire Rescue Department and have held that position for approximately seven (7) years. As a Specialist, I serve as an advisor to the Office of the Fire Marshal.

OPINION

You asked whether the Restore Hyper Wellness locations are required to comply with National Fire Protection Association ("NFPA") 99, Chapter 14. Chapter 1.1.12 of NFPA 99 states that Chapter 14 applies to "Hyperbaric Facilities." In my view, the Restore Hyper Wellness locations are not "Hyperbaric Facilities." The reason is that the Restore Hyper Wellness locations are not using the chambers to provide hyperbaric medical treatment to occupants.

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Indeed, the chambers operate with atmospheric pressures below 1.4 Atmospheres Absolute (ATA). The Undersea and Hyperbaric Medical Society has determined that atmospheric pressures below 1.4 ATA do not constitute hyperbaric medical treatment. As such, the Hyper Wellness Locations are not "Hyperbaric facilities" as defined in Chapter 3.3.80 NFPA 99. Therefore, NFPA 99, Chapter 14 does not apply to the Restore Hyper Wellness locations, and thus the Restore Hyper Wellness locations are not required to comply with any provisions in NFPA 99, Chapter 14.

You also asked whether, assuming in the alternative that NFPA 99, Chapter 14 does apply to the Restore Hyper Wellness locations, such locations fall under Category 3 Hyperbaric Care. Chapter 14.1.3.3 of NFPA 99 explains what constitutes Category 3 Hyperbaric Care. Chapter 14.1.3.3.1 states that "[w]here interruption or failure of medical gas supply is not likely to cause injury to patients, staff, or visitors, the medical gas system shall be considered Category 3 for use in this chapter." In my view, this Chapter does not apply to the Restore Hyper Wellness locations because the compressors that they are using to supply air to the chamber is not a medical gas supply. A medical gas supply is a gas (medical air or other gas) that meets certain Compressed Gas Association (CGA) standards. Restore Hyper Wellness compressors simply compress the room air (21% oxygen, 78% nitrogen, 1% other gasses). The Restore Hyper Wellness locations are simply supplying air to the chamber. For a medical gas supply to exist, the compressed air must be filtered, tested for oxygen concentration, and tested for possible carbon monoxide. Once this happens, that is when the air supplied to the chamber is pure and becomes a medical gas supply. That does not exist at the Restore Hyper Wellness locations.

Chapter 14.1.3.3.2 states that "[w]here interruption or failure of electrical service is not likely to cause injury to patients, staff, or visitors, the medical gas system shall be considered Category 3 for use in this chapter." In my view, the electric service is the electricity that provides power to the compressors. If there is an interruption of electricity, the compressors would no longer supply air to the chamber and the chambers would therefore simply deflate on their own. When ambient pressure is reached, the occupant can self-evacuate.

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Simply put, there is no possibility of occupants, staff, or visitors being injured due to an interruption or failure of the compressors. Therefore, in my opinion, the Restore Hyper Wellness locations fall under Category 3 Hyperbaric Care, NFPA 99, Chapter 14.1.3.3.2.

For general safety and soundness purposes and without regard for whether NFPA 99, Chapter 14 in fact applies, you asked my opinion regarding how the Restore Hyper Wellness locations could reasonably reduce the risk of a fire occurring inside the chambers and therefore comply with the relevant provisions of NFPA 99, Chapter 14. You also asked my opinion regarding how Restore Hyper Wellness locations could reasonably reduce the risk of an injury to an occupant when a fire occurs outside the chambers and therefore comply with the relevant NFPA 99, Chapter 14.

Before giving my recommendations, I would like to point out that not every provision in NFPA 99, Chapter 14 applies to the use of the chambers at the Restore Hyper Wellness locations. The provisions that do apply are designed to reasonably reduce the risk of an injury to an occupant as the result of a fire inside and outside the chambers.

That being said, I recommend that Restore Hyper Wellness locations develop and implement a written policy that prohibits occupants from having the following items inside the chambers: (1) personal warming devices, such as therapeutic chemical heating pads, hand warmers, pocket warmers, (2) cell phones and pagers, (3) sparking toys, and (4) personal entertainment devices. I also recommend that the Restore Hyper Wellness locations use water-proof radios if they elect to include radios inside their chambers as a safety measure. By following this recommendation, the Restore Hyper Wellness locations will eliminate all potential ignition sources inside the chambers, which will eliminate the possibility of a fire occurring inside the chambers. This alone should eliminate any concern that a fire marshal may have regarding the potential of a fire occurring inside the chambers.

Even though adopting the recommendation above will eliminate the possibility of a fire occurring inside the chambers, there are a few other relevant sections in NFPA 99, Chapter 14.

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In that regard, I recommend that Restore Hyper Wellness locations post a sign in the room where the chamber is located that states that occupants are prohibited from bringing flammable liquids and or gases into the chambers. I also recommend that Restore Hyper Wellness locations have a telephone inside the space where the chamber is located so that an occupant could dial 911 in the event of a fire. If there is a central fire alarm system already installed in the building, a fire-pull station should be in the space where the chamber is located.

I recommend that the Restore Hyper Wellness locations develop and implement a written policy that prohibits the use of a battery-operated fan/light inside the chambers. Even though the risk of a fire inside the chambers is low, disallowing the use of a battery-operated fan/light inside would lower that risk even further.

I also recommend that the Restore Hyper Wellness locations develop and implement a written policy requiring that the air from the compressors be sampled every six (6) months to ensure that the air being supplied to the chambers is safe. The Restore Hyper Wellness locations can order an air sampling kit from a laboratory. The air sampling kit is attached to the compressor and obtains a sample of the air. The sample is then sent back to the laboratory so that the laboratory can then communicate to the locations whether the purity of the sampled air.

I also recommend that Restore Hyper Wellness locations designate and train one employee to be responsible for fire safety at each location. I recommend that Restore Hyper Wellness locations have a written emergency action plan, which is a blueprint on how to evacuate in the event of an emergency, including a fire. Employees should be trained on the emergency action plan, and the training documented. I recommend that the Restore Hyper Wellness locations conduct and document an annual fire drill.

I am now going to address provisions in NFPA 99, Chapter 14 that, in my opinion, are not relevant to the chambers at the Hyper Wellness Locations.

I do not recommend that Restore Hyper Wellness locations install an exhaust system on the chambers that would lead to the exterior of the building.

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The reason is that the exhaust from the chambers would be room air. Thus, there are no safety reasons why the chambers should be vented to the atmosphere outdoors. Exhaust systems are required for hyperbaric care facilities when the chambers are compressed with 100% oxygen. Because if the chamber were to exhaust 100% oxygen into the atmosphere of the room, this would create a fire hazard. That does not exist at the Restore Hyper Wellness facilities. The exhaust is simply the same ambient air found in the room.

I do not recommend that Restore Hyper Wellness locations require occupants to restrict the type of clothing that they wear while inside the chambers. The reason is that the

chamber is compressed with air and not 100% oxygen. If a chamber is compressed with 100% oxygen, fabrics that cause static need to be prohibited so that they do not serve as an ignition source to start a fire. That does not exist at the Restore Hyper Wellness locations.

I do not recommend that the Restore Hyper Wellness locations modify the chambers to include emergency lighting inside the chambers. The reason is that the occupants do not need a light inside the chambers to help them get out in the event of an emergency. In any event, the chambers have at least one clear window so that occupants have lighting from the room that is housing the chambers. Simply put, the occupants inside the Restore Hyper Wellness locations do not need lighting inside the chambers in the event of an emergency.

I do not recommend that the Restore Hyper Wellness locations have an independent source of power. The reason is that if there is an interruption of electricity, the compressors would no longer supply air to the chamber and the chambers would therefore simply deflate on their own. When ambient pressure is reached, the occupant can self-evacuate. Simply put, there is no possibility of occupants, staff, or visitors being injured due to an interruption or failure of the compressors or other power source.

I do not recommend that the Restore Hyper Wellness locations modify the chambers to include an oxygen monitor.

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The reason is that an oxygen monitor is only necessary when the atmosphere inside a chamber reaches an oxygen level of 23.5% or higher. This is because anytime an oxygen level is 23.5% or higher, it poses a risk of fire from static electricity. As a result, when the oxygen level reaches 23.5% or higher inside the chamber, an oxygen monitor with an audible alarm can warn the operator of the chamber to increase ventilation, thereby lowering the oxygen concentration to eliminate the risk of a fire inside. Test results show that the oxygen levels inside the Restore Hyper Wellness chambers do not reach 23.5%, they never exceed 22% oxygen.

For the same reasons given above that the Restore Hyper Wellness locations do not need to include an oxygen monitor – the oxygen levels do not reach 23.5% inside the chambers - I do not recommend that the Restore Hyper Wellness locations ground the chambers, ground the occupants while inside the chambers, prohibit occupants from

using hair sprays, hair oils, skin oils, cosmetics, and lotions, or mandate that all other fabrics inside the chambers be at least 50% percent cotton, as there is absolutely no safety value in doing any of these things.

Applicability of ASME-PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy (An American National Standard) – This code language was written primarily to address multiplace (NFPA Class A) and monoplace (NFPA Class B) chambers. Class A chambers can be designed to reach very deep pressures (at times greater than 1,000 feet of sea water for some specific research applications) and are usually compressed with medical grade air and provide other gas mixtures (at times hypoxic gas mixtures) via a Built-In Breathing System (BIBS). Monoplace chambers are typically designed to reach a maximum pressure of 66 feet of sea water (3.0 ATA) and are usually compressed with 100% medical grade oxygen. Both Class A and B chambers consist of complex systems; at times the chamber occupants are confined, and unable to ascend to surface pressure and evacuate the chamber, for a considerable amount of time due to the administration of inert gasses such as nitrogen and/or or helium in combination with oxygen (NITROX / HELIOX).

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In other words, occupants of these chambers are at times subject to lengthy decompression schedules and require the attendance of specially trained medical staff, chamber operators, and inside technologists. Soft shell chambers, such as the ones in use at Restore Hyper Wellness locations, were not considered in the writing of ASME-PVHO-1, therefore the code does not specifically address the application of these systems and how these chambers are typically utilized. These chambers are designed and engineered to achieve relatively low pressures (just a few feet of sea water, or PSI's, greater than ambient atmospheric pressure) and are designed to be compressed solely with room air (not medical air or any other medical gas). The occupant can safely self-evacuate the chamber at any point without the possibility of any ill-effects. Therefore, it is my opinion that the code language in ASME-PVHO-1 is not applicable to the soft-shell chambers in the way they are used by Restore Hyper Wellness locations.

Applicability of ASME-PVHO-2, Safety Standard for Pressure Vessels for Human Occupancy In-Service Guidelines for Acrylic Windows (An American National Standard) – This code language was written to specifically address chamber acrylic windows. Soft shell chambers, such as the ones in use at Restore Hyper Wellness locations, are not equipped with acrylic windows. Therefore, it is my opinion that the code language in ASME-PVHO-2 is not applicable to the soft-shell chambers used by Restore Hyper Wellness locations.

Sincerely,

Mario Caruso

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FIRE PROTECTION & LIFE SAFETY ANALYSIS

RESTORE HYPER WELLNESS + CRYOTHERAPY
MILD HYPERBARIC OXYGEN THERAPY CHAMBER
[ADDRESS]
[ADDRESS]
[DATE]

Fire Protection Engineer

Report Prepared for:
Paul Szymanksi
Restore Hyper Wellness + Cryotherapy

Report Created by:
[XXXXXXXXXXX]
[XXXXXXXXXXX]
[XXXXXXXXXXX]
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Page project #422155.XX

Revision	Description	Date
0	Fire Protection & Life Safety Analysis - mHbOT chamber	[X/XX/XX]

Contents

1. EXECUTIVE SUMMARY

This report evaluates the Fire Protection & Life Safety provisions related to the mild Hyperbaric Oxygen Therapy (mHbOT) equipment and service provided at the Restore Hyper Wellness store located at [_____]. This report provides specific recommendations and requirements that should be implemented at the Restore Hyper Wellness center which houses the mHbOT equipment based on engineering judgment, engineering best practices, and compliance with local requirements.

2. mHbOT HYPERBARIC CHAMBER OVERVIEW

Restore operates wellness centers nationwide offering mild Hyperbaric Oxygen Therapy (mHbOT) as well as other therapeutic services in a non-hospital setting. The purpose of this report is to address the mild Hyperbaric Oxygen Therapy chamber from a fire protection and life safety prospective.

This therapy is conducted as the client enters a soft sided chamber where they are exposed to higher levels of oxygen compared to the ambient air. This report addresses the fire protection and life safety aspects related to this therapy and provides criteria to ensure a reasonable level of protection is provided to the occupants.

The key components when analyzing the mHbOT chamber include:

- Oxygen chamber - Soft sided, sitting or lying down models.
- Air compressor - Used to supply fresh ambient air to the interior of the chamber and inflate the chamber to ~30-40% higher levels of atmospheric pressure (~4 psig higher)
- Oxygen concentrator - This device concentrates the oxygen in room air to about 95% and delivers it to the client using a nasal cannula.

For this therapy, the client enters a soft sided chamber and either sits in the chamber or lies down in the chamber, depending on the model. A typical chamber used for lying down can be seen in the image below:

Figure 1: Typical mHbOT Chamber

After the client enters the chamber, the trained personnel goes over all safety procedures with the client, zips the mHbOT chamber closed and starts the air compressor. Over the course of roughly 5 minutes, the chamber becomes pressurized and relatively rigid. A relief valve is designed into the chamber to prevent over pressurization and the interior pressure can be read from outside of the chamber with a pressure gauge. Once the chamber is pressurized, the oxygen concentrator is turned on by the trained personnel.

The air compressor and oxygen concentrator are two separate machines located outside and adjacent to the mHbOT chamber. For these chambers, pure oxygen is not utilized so there are no oxygen cylinders required. Utilizing the air compressor and oxygen concentrator to make oxygen when it is needed mitigates the fire hazard associated with compressed oxygen cylinder storage and use. The 95% oxygen is concentrated from room air and the concentrator power is supplied by the regular building power.

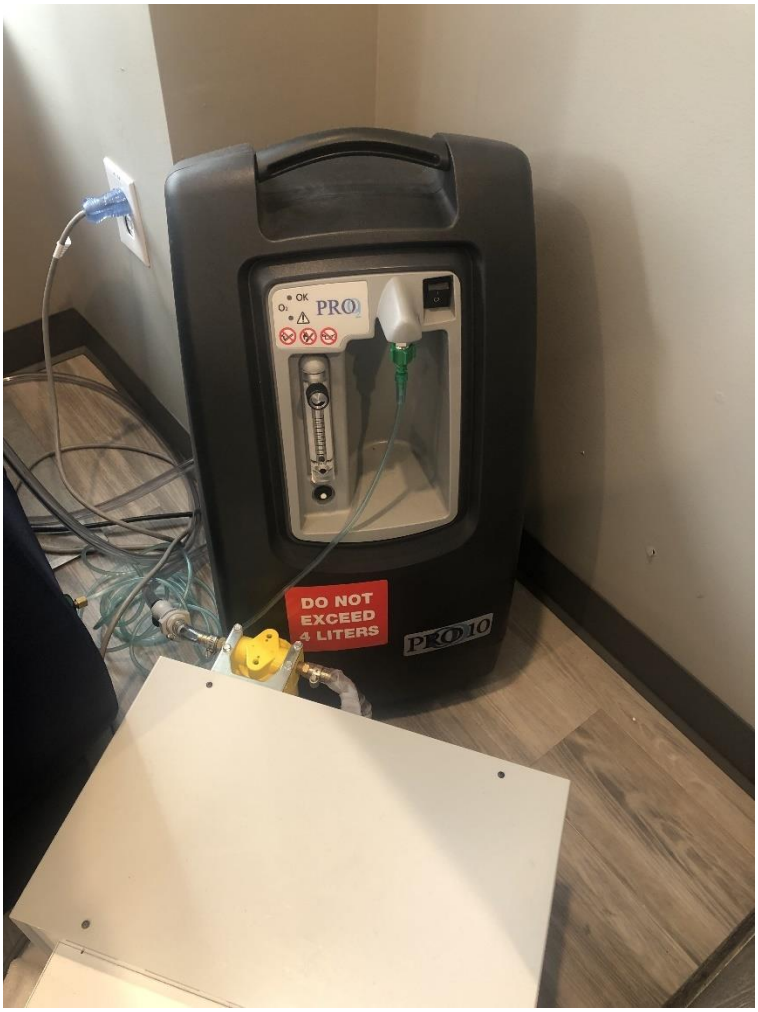


Figure 2: Air Compressor and Oxygen Concentrator

3. APPLICABLE CODES

This analysis is based on the following codes applicable in [_____]

- [____] International Building Code
- [____] International Fire Code
- [_____] NFPA 10, *Standard for Portable Fire Extinguishers*
- [____] NFPA 13, *Standard for the Installation of Sprinkler Systems*
- [____] NFPA 70, *National Electrical Code*
- [____] NFPA 72, *National Fire Alarm and Signaling Code*
- [____] NFPA 99, *Health Care Facilities Code*

4. BUILDING INFORMATION

4.1 SITE LAYOUT AND LOCATION

The Restore Hyper Wellness building with the mHbOT chamber is located at [_____]. The [building is a standalone structure] [tenant space is part of a larger retail center]. The site has direct fire department access and fire hydrants within [_____] feet of the store. An aerial image is provided below with the hydrant locations and store location identified.

[INSERT AERIAL IMAGE WITH HYDRANTS AND STORE IDENTIFIED]

Figure X: Aerial View of Site Layout

4.2 BUILDING DESCRIPTION

The building is classified as Type [__] construction which means that the building is constructed of [noncombustible] [combustible] materials [with] [without] fireproofing. The building is [__] story, has a project area of [____] square feet, and was built in [___]. This information is based on [field observations] [existing building plans].

4.2.1 OCCUPANCY CLASSIFICATION & SEPARATION

The Restore Hyper Wellness space is classified as a business occupancy. Occupant load and egress criteria for the building such as travel distance, common path of travel, and dead-end corridors must meet the requirements for a [business] occupancy. [Other tenants in the same building footprint are Group A, Group B, or Group M occupancies.] [The occupancy classification of the Restore Hyper Wellness space is consistent with the occupancy classification for the rest of the building and does not require any separation] [The Restore Hyper Wellness space is required to be separated by a [_]-hour rating from the adjacent spaces to meet occupancy separation requirements].

5. FIRE PROTECTION & LIFE SAFETY ANALSYIS - BUILDING

5.1 FIRE SUPPRESSION

5.1.1 AUTOMATIC FIRE SPRINKLERS

[The suite where mHbOT chamber is located does not require a fire sprinkler system to be installed. Therefore, there is no consideration for fire sprinklers within the mHbOT chamber.]

[The [building] [Restore Hyper Wellness tenant suite] is required to have automatic sprinkler coverage. [The riser room is located in [_____] and the building is protected with a wet-pipe sprinkler system.] [The sprinkler coverage as designed is adequate for the [light hazard] [ordinary hazard (group 1)] occupancy classification.]

Since the mHbOT is not a permanent chamber or considered an obstruction to the general sprinkler coverage in the space, additional consideration for sprinkler requirements within the chamber is not

required. Additionally, there is no practical method of installation based on how the mHbOT chamber changes size and configuration when it is pressurized and depressurized.

5.1.2 STANDPIPES

The building is [not] required to have a standpipe system and one is [not] provided. [The closest hose valve in relation to the Restore Wellness store is [_____] feet]. [The travel distance requirement of 200 feet to any occupied space is met].

5.1.3 PORTABLE FIRE EXTINGUISHERS

Portable fire extinguishers are [not] required and are [not] provided. [The fire extinguishers are spaced appropriately for the tenant space with regards to travel distance requirements as required by NFPA 10.]

5.1.4 WATER SUPPLY

[A city water supply] [A fire water tank and fire pump] provide[s] water for the hydrants located at the site. [The same water mains supplying the hydrants also supply the fire sprinkler system for the building.] The pressure information for the site was determined to be a static pressure of [____] psi and a residual pressure of [____] psi with [____] GPM flowing.

5.2 FIRE ALARM

[With regards to code minimum requirements, The Restore Hyper Wellness space [as a Group B occupancy] does not require a manual fire alarm system and occupant notification based on the locally adopted codes. However, a fire alarm system should be provided based on the fire protection and life safety analysis of the mHbOT chamber. See Section 6.4 for additional information.]

[The Restore Hyper Wellness space [as a Group [__] occupancy] does require a manual fire alarm system and occupant notification based on the locally adopted codes. The system shall be designed and installed in accordance with the [_____] and NFPA 72. See Section 6.4 for additional information.]

5.3 SMOKE CONTROL

A smoke control system is not required for the Restore Hyper Wellness space, and one is not provided.

5.4 LIFE SAFETY

5.4.1 MEANS OF EGRESS

[The Restore Wellness suite has adequate egress with [___] exits from the space.] [There are no dead-end corridors exceeding the allowable limit and both common path and travel distance requirements are met.] [The exit discharge is sufficient for the building occupant load.] Refer to Section 6.4 for further analysis of the egress as it relates to the mHbOT Chamber.

5.4.2 EMERGENCY LIGHTING

Exit signs and emergency lighting for egress are [not] required [and provided adequately for the space].

6. FIRE PROTECTION & LIFE SAFETY ANALYSIS – mHbOT CHAMBER

6.1 CHAMBER EQUIPMENT

The equipment utilized for the mHbOT chamber includes the oxygen chamber, the air compressor, and the oxygen concentrator. All equipment must be used as intended and in accordance with the manufacturer's standards.

6.2 CHAMBER ATMOSPHERE

Chapter [14] [__] of NFPA 99 covers the requirements for Class A, B, and C hyperbaric facilities for health care facilities. NFPA 99 includes many requirements for oxygen-enriched atmospheres that are not applicable for the mHbOT chambers utilized by Restore Hyper Wellness. Per NFPA 99, an *oxygen-enriched atmosphere* is an atmosphere in which the concentration of oxygen exceeds 23.5% by volume. Restore Hyper Wellness hired a testing laboratory to complete atmospheric testing, and the assessment completed by Eurofins Met Labs determined that the oxygen concentration was no higher than 23.1% during the tests. The results of these tests, located in Appendix [B] [__], were completed with two different set-ups. The first scenario placed the oxygen mask directly on the client inside the chamber and the second scenario placed the oxygen mask next to the client inside the chamber.

The level of oxygen concentration inside the chamber during the therapy is critical because the burning characteristics of combustibles can change dramatically in oxygen-enriched environments. NFPA 99 has additional requirements for oxygen-enriched atmospheres because of the increase in combustibility. However, the operating oxygen concentration of the mHbOT chamber does not exceed the critical 23.5% threshold as long as procedures are followed by the trained personnel. Additionally, the staff is trained and signage is posted on the oxygen concentrator to limit the supply to four liters.

While Page does not believe the chamber is required to comply with NFPA 99 by definition, there are guidelines and reasonable requirements that should be met to achieve a similar level of life safety.

6.3 APPLICABILITY OF NFPA 99

As mentioned previously, not all of NFPA 99 will apply to the mHbOT chamber due to the atmosphere being lower than 23.5% oxygen concentration. The following list includes relevant code sections that address specific requirements from the 2021 edition of NFPA 99 for mHbOT chambers:

- 14.1.1.1 – The facility shall be treated as new
- 14.1.2.2 – The chamber shall be classified as a Class B chamber.
- 14.2.1.1.2 – The Class B chamber shall not be required to be protected by a 2-hour fire resistant rated construction.

- 14.2.1.1.5 – Exterior walls forming part of the facility boundary shall not require 2-hour fire resistant rated construction.
- 14.2.1.1.8 – Service equipment shall be permitted to be located in multi-use spaces.
- 14.2.1.1.9 – The supporting foundation for any chamber shall be designed to support the chamber.
- 14.2.1.2.2 – The room housing a Class A, Class B, or Class C chamber shall contain a minimum of one 2-A:10B:C portable fire extinguisher.
- 14.2.4.4 – The minimum ventilation rate for a Class B chamber shall be 0.0283 m^3/min (1 ft^3/min)
- 14.2.4.4.3 – For Class B chambers equipped with a breathing apparatus, the breathing apparatus shall function at all pressures that can be encountered in the chamber.
- 14.2.5 – Class B chambers shall be capable of depressurizing from 3 ATA to ambient pressure in not more than 2 minutes.
    1. The mHbOT chamber meets this as the zippers can be forced open in the event of an emergency. The longer depressurization process is conducted in non-emergency situations for the comfort of the client.
- 14.2.8 – Class B and Class C chambers shall not be required to comply with 14.2.6 which requires fire protection systems for Class A chambers.
- 14.2.8.1 – Signs prohibiting the introduction of flammable liquids, gases, and other articles not permitted by chapter 14 of NFPA 99 into the chamber shall be posted in the room the chamber is located.
- 14.2.8.2 – A means for communication shall be provided within the room housing the chamber(s) for notifying the fire department.
    1. The requirement from the fire protection and life safety analysis for a pull station in the mHbOT chamber room satisfies this requirement.
- 14.2.8.2.1 – If the building housing the hyperbaric facility has a central fire alarm system, the communication shall be a pull-station connected to the system.
- 14.2.9.1.1 – The requirements of NFPA 70 or local electrical codes shall apply to electrical wiring and equipment in hyperbaric facilities within the scope of NFPA 99 Chapter 14.
- 14.2.9.1.2 – All hyperbaric chamber service equipment, switchboards, panels, or control consoles shall be located outside of, and in the vicinity of, the chamber.
- 14.2.9.1.4 – For the fixed electrical installation, none of the following shall be permitted inside the chamber:
    1. Circuit breakers
    2. Line fuses
    3. Motor controllers
    4. Relays
    5. Transformers
    6. Ballasts
    7. Lighting panels
    8. Power panels
- 14.3.1.1 – Section 14.3 contains requirements for administration and maintenance that shall be followed as an adjunct to physical precautions specified in Section 14.2

- 14.3.1.5.1 – Emergency procedures specific to the hyperbaric chamber shall be established.
- 14.3.1.5.2 – All personnel shall be trained in emergency procedures.
- 14.3.1.5.3 – Personnel shall be trained to control the chamber and decompress occupants when all powered equipment has been rendered inoperative.

6.4 EGRESS CONSIDERATIONS

During occupant egress, the primary goal is for all occupants to evacuate the building in the required time before conditions in the space become untenable and hazardous. The bottom line in egress analyses is for the required safe egress time (RSET) to be less than the available safe egress time (ASET) to ensure all occupants are able to safely evacuate the building. The RSET includes the time to notification, pre-movement time, and evacuation time. The ASET begins with the ignition of the fire and ends when the space reaches tenability limits. The major components of the RSET are detailed further below:

Time to notification: The time between the ignition and the when an alarm sounds or when occupants become aware of the fire.

Pre-movement time: The time that it takes for the occupant between when they decide to egress and when they begin heading in the direction of an exit. This time could include the gathering of belongings, shutting down equipment, waiting for other people, or putting on a jacket.

Evacuation time: The time required to move to a safe location (in this case outside the store).

With the mHbOT chamber at Restore Hyper Wellness, the egress analysis must consider the self-initiated depressurization process. Though the intent and standard practice is to always have the egress be guided and assisted, the egress analysis was performed with worst case scenarios in mind and the assumption that the attendant is otherwise unavailable to assist. Page reviewed a series of self-egress testing videos performed at various Restore locations to quantify occupant self-egress time from the chamber (See Appendix A). Based on the results of the test, the average occupant self-egress time was two minutes and twenty-five seconds. None of the self-egress times exceeded three minutes. (Note: The depressurization process can be expedited by forcing open the zippers in the event of an emergency where imminent danger is present. This action is reserved for emergencies only since the accelerated pressure change may produce minor discomfort in the inner ear for the occupant.)

When compiling the RSET for the mHbOT circumstance, most of the required egress time is categorized as pre-movement time as the chamber must be depressurized and then the zippers unzipped to allow the occupant to begin egressing. As stated above, the time for chamber depressurization is about two minutes and twenty-five seconds (with none greater than three minutes). This pre-movement time is anticipated to be longer than that of other Group B occupancies, in which case occupants may gather belongings or check with other co-workers before egressing. Per Table 64.4 of the *2016 SFPE Handbook*, pre-movement times for these Group B occupancies is approximately one minute or less. For this reason, additional requirements are required to offset this increase in pre-movement time. These requirements are outlined in Section 7 of this report, in which Page believes compliance with either option 2a or 2b mitigates the concern regarding increased pre-movement egress times.

7. REQUIREMENTS

This section is intended to summarize the requirements in the Restore facility related to the mHbOT chamber. In summary, there are specific requirements that should be met from NFPA 99 and additional safeguards to help address egress concerns for occupants using the chamber.

1. Refer to Section 6.3 of this report for line by line requirements for the mHbOT chamber and the Restore tenant space. Some of these requirements are the responsibility of the owner, some are incorporated by the equipment manufacturer, and others can be included in the design of the Tenant Suite by the Architect and Engineer of record.

2. Due to the differences in the RSET for the Restore space containing the mHbOT equipment and other Group B occupancies (particularly regarding the pre-movement time), Page has provided additional criteria that shall be followed based on the analysis. These requirements are made under the assumption that the applicable building code does not require and the Restore tenant space is not provided with an automatic sprinkler system or fire alarm system. One of the following requirements shall be met for the Restore Hyper Wellness containing an mHbOT chamber:

    a. A full addressable fire alarm and detection system to be installed in accordance with NFPA 72. This would cover the entire Restore occupied space [and be connected to the base building fire alarm system for monitoring]. This fire alarm system shall have full spot type smoke detection coverage. Manual pull stations shall be provided at each of the exits as well as one in the mHbOT chamber room. Having both automatic smoke detection and manual initiation of the fire alarm system will ensure occupant egress begins as early as possible. Notification coverage per NFPA 72 shall be provided throughout the facility, including audible and visible notification appliances in the mHbOT chamber room. The notification appliance located in the mHbOT chamber room shall be located to provide optimal visual coverage into the chamber where possible. Operating procedures should be in place for occupants to begin self-depressurization as soon as any notification device activates.
        I. In addition to the fire alarm system, the mHbOT chamber room shall be located so that travel distance to the nearest exit is less than 100 feet.

    b. The mHbOT room shall be configured to have direct egress to the exterior of the [tenant space] [building] in addition to the primary entrance/exit of the tenant space (i.e. a minimum of two means of egress). This shorter egress distance will help reduce the RSET and allow for multiple egress options for the occupant. The room shall also be constructed with smoke partitions and a self-closing door to limit the passage of smoke into the room while the occupant is depressurizing.

APPENDIX A: RESTORE EGRESS TESTING

Location	mHbOT Type	Distance to exit (linear feet)	Duration (minutes)	Test Subject Age	Test Subject Sex	Test Subject Height
Mueller	Vitaeris	70’-10”	2:00	26	M	5’-5”
River Oaks	Oxyflow Sitting	56’-6”	1:57	49	F	5’-6”
Sugarland	Oxyflow Sitting	47’-7”	2:42	34	F	5’-3”
N Scottsdale	Oxyflow Sitting	89’-5”	2:39	30	M	6’-0”
N Bethesda	Oxyflow Sitting	103’-5”	2:50	23	M	5’-9”

APPENDIX B: EUROFINS/MET LABS TEST REPORT

HEADQUARTERS: 914 WEST PATAPSCO AVENUE • BALTIMORE, MARYLAND 21230 • PHONE (410) 354-3300 • FAX (410) 354-3313

November 14, 2021

Mr. Paul Szymanski
Austin Cryo Ventures, LLC dba Restore Hyper Wellness
3601 S Congress Ave., Suite C200
Austin, Texas 78704
USA

Subject: Mild Hyperbaric Chamber
MET Project Number 115944

Dear Mr. Szymanski:

The mild hyperbaric chambers listed below were tested per the operating procedure provided by Austin Cryo Ventures, LLC dba Restore Hyper Wellness:

OxyHealth Vitaeris 320 with AIRSEP Concentrator
Oxyflow Sitting Soft Chamber with Canta Concentrator Unit
Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit

Eurofins E&E has determined that at 4.0 LPM and a pressure of ~ 4.1 psi, the oxygen concentration inside the chambers did not exceed 23.5% under all tested scenarios with mask on or off; therefore, it did not create an oxygen enriched environment as defined by NFPA 99. Please see the attached test datasheets for detailed results.

Thank you for the opportunity to perform this service for Austin Cryo Ventures, LLC dba Restore Hyper Wellness. We look forward to future opportunities with your company.

Sincerely,
MET LABORATORIES, INC.

Johanna Goforth
General Manager,
Austin Safety Laboratory

Test Performance Letter
Test Data Report

Manufacturer/Applicant:

Cryo Ventures, LLC dba Restore Hyper Wellness
3601 S Congress Ave., Suite C200, Austin, TX 78704
{OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit}

Mild Hyperbaric Chamber

Eurofins Electrical and Electronic Testing North America, Inc.

13501 McCallen Pass
Austin, Texas 78753
(512) 287-2500

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		

Oxygen Concentration verification based on 4LPM per client's SOP

Date:	11/09/2021 ☒ Initial Test	☐ Retest #	
Tested by:	Jimmy Cox	Date:	11/09/2021
Setup verified by:	Kamran Sheikh	Date:	11/09/2021
Data reviewed by:	Johanna Goforth	Date:	11/12/2021
Temperature: (°C)	20.8	Relative Humidity: (%RH)	57.0
Pressure: (kpa)	99.07		

Test Results: Completed	☐Compliance:	☐Continued Compliance:	☒ Engineering only:

OxyHealth Vitaeris 320 with mask on

Time on 11/09/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
11:05 a.m.	20.9	4.0	4.1	No
11:10 a.m.	21.2	4.0	4.1	No
11:15 a.m.	21.6	4.0	4.1	No
11:20 a.m.	21.7	4.0	4.1	No
11:25 a.m.	21.8	4.0	4.1	No
11:30 a.m.	22.2	4.0	4.1	No
11:35 a.m.	22.4	4.0	4.1	No
11:40 a.m.	22.3	4.0	4.1	No
11:45 a.m.	22.2	4.0	4.1	No
11:50 a.m.	22.1	4.0	4.1	No
11:55 a.m.	22.2	4.0	4.1	No
12:00 p.m.	22.1	4.0	4.1	No
12.05 p.m.	22.1	4.0	4.1	No
12:10 p.m.	22.1	4.0	4.1	No
12:15 p.m.	22.0	4.0	4.1	No
12:20 p.m.	22.1	4.0	4.1	No
12:25 p.m.	22.2	4.0	4.1	No
12:30 p.m.	22.3	4.0	4.1	No
12:35 p.m.	22.3	4.0	4.1	No

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		

Test Results: Completed	☐ Compliance:	☐ Continued Compliance:	☒ Engineering only:

OxyHealth Vitaeris 320 with mask off

Time on 11/09/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
1:30 p.m.	20.9	4.0	4.1	No
1:35 p.m.	21.1	4.0	4.1	No
1:40 p.m.	21.4	4.0	4.1	No
1:45 p.m.	21.6	4.0	4.1	No
1:50 p.m.	21.8	4.0	4.1	No
1:55 p.m.	22.2	4.0	4.1	No
2:00 p.m.	22.0	4.0	4.1	No
2:05 p.m.	22.0	4.0	4.1	No
2:10 p.m.	22.6	4.0	4.1	No
2:15 p.m.	22.2	4.0	4.1	No
2:20 p.m.	22.5	4.0	4.1	No
2:25 p.m.	22.1	4.0	4.1	No
2:30 p.m.	22.2	4.0	4.1	No
2:35 p.m.	22.3	4.0	4.1	No
2:40 p.m.	22.0	4.0	4.1	No
2:45 p.m.	22.1	4.0	4.1	No
2:50 p.m.	22.0	4.0	4.1	No
2:55 p.m.	22.0	4.0	4.1	No
3:00 p.m.	22.3	4.0	4.1	No

Test Results: Completed	☐ Compliance:	☐ Continued Compliance:	☒ Engineering only:

OxyAir 32 Horizontal mask on

Time on 11/09/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
3:55	20.9	4.0	4.0	No
4:00 p.m.	21.8	4.0	4.0	No
4:05 p.m.	22.2	4.0	4.0	No
4:10 p.m.	22.5	4.0	4.0	No
4:15 p.m.	22.6	4.0	4.0	No
4:20 p.m.	22.7	4.0	4.0	No
4:25 p.m.	22.7	4.0	4.0	No
4:30 p.m.	22.7	4.0	4.0	No
4:35 p.m.	22.7	4.0	4.0	No

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		

4:40 p.m.	22.7	4.0	4.0	No
4:45 p.m.	22.7	4.0	4.0	No
4:50 p.m.	22.8	4.0	4.0	No
4:55 p.m.	22.7	4.0	4.0	No
5:00 p.m.	22.7	4.0	4.0	No
5:10 p.m.	22.7	4.0	4.0	No
5:15 p.m.	22.7	4.0	4.0	No
5:20 p.m.	22.7	4.0	4.0	No
5:25 p.m.	22.7	4.0	4.0	No

Test Results: Completed ☐ Compliance: ☐ Continued Compliance: ☒ Engineering only:

OxyAir 32 Horizontal mask off

Time on 11/10/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
9:40 a.m.	21.5	4.0	4.0	No
9:45 a.m.	22.1	4.0	4.0	No
9:50 a.m.	22.4	4.0	4.0	No
9:55 a.m.	22.6	4.0	4.0	No
10:00 a.m.	22.8	4.0	4.0	No
10:05 a.m.	22.8	4.0	4.0	No
10:10 a.m.	22.8	4.0	4.0	No
10:15 a.m.	22.9	4.0	4.0	No
10:20 a.m.	22.9	4.0	4.0	No
10:25 a.m.	23.0	4.0	4.0	No
10:30 a.m.	23.1	4.0	4.0	No
10:35 a.m.	22.8	4.0	4.0	No
10:40 a.m.	22.8	4.0	4.0	No
10:45 a.m.	22.8	4.0	4.0	No
10:50 a.m.	22.8	4.0	4.0	No
10:55 a.m.	22.8	4.0	4.0	No
11:00 a.m.	22.8	4.0	4.0	No
11:05 a.m.	22.8	4.0	4.0	No
11:10 a.m.	22.8	4.0	4.0	No

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		

Test Results: Completed	☐Compliance:	☐Continued Compliance:	☒ Engineering only:

Oxy-Flow Sit Up mask on

Time on 11/10/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
12:05 p.m..	20.8	4.0	4.5	No
12:10 p.m.	22.0	4.0	4.5	No
12:15 p.m.	22.0	4.0	4.5	No
12:20 p.m.	22.0	4.0	4.5	No
12:25 p.m.	22.0	4.0	4.5	No
12:30 p.m.	22.0	4.0	4.5	No
12:35 p.m.	22.0	4.0	4.5	No
12:40 p.m.	22.0	4.0	4.5	No
12:45 p.m.	22.0	4.0	4.5	No
12:50 p.m.	22.0	4.0	4.5	No
12:55 p.m.	22.0	4.0	4.5	No
1:00 p.m.	22.0	4.0	4.5	No
1:05 p.m.	22.1	4.0	4.5	No
1:10 p.m.	22.1	4.0	4.5	No
1:15 p.m.	22.1	4.0	4.5	No
1:20 p.m.	22.1	4.0	4.5	No
1:25 p.m.	22.1	4.0	4.5	No
1:30 p.m.	22.1	4.0	4.5	No
1:35 p.m.	22.1	4.0	4.5	No

Test Results: Completed	☐Compliance:	☐Continued Compliance:	☒ Engineering only:

Oxy-Flow Sit Up mask off

Time on 11/10/2021	02 %	Verification Only		>23.5% 02
		LPM	PSI	
2:50 p.m.	20.9	4.0	4.5	No
2:55 p.m.	21.4	4.0	4.5	No
3:00 p.m.	21.6	4.0	4.5	No
3:05 p.m.	21.8	4.0	4.5	No
3:10 p.m.	22.2	4.0	4.5	No
3:15 p.m.	22.3	4.0	4.5	No
3:20 p.m.	22.4	4.0	4.5	No
3:25 p.m.	22.6	4.0	4.5	No
3:30 p.m.	22.6	4.0	4.5	No
3:35 p.m.	22.6	4.0	4.5	No
3:40 p.m.	22.7	4.0	4.5	No

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		

3:45 p.m.	22.7	4.0	4.5	No
3:50 p.m.	22.8	4.0	4.5	No
3:55 p.m.	22.7	4.0	4.5	No
4:00 p.m.	22.7	4.0	4.5	No
4:05 p.m.	22.8	4.0	4.5	No
4:10 p.m.	22.9	4.0	4.5	No
4:15 p.m.	22.9	4.0	4.5	No
4:20 p.m.	22.8	4.0	4.5	No
4:25 p.m.	22.7	4.0	4.5	No

Setup description:	Each chamber was fitted with a ¼ tube and the internal oxygen levels were sampled through the 02 Analyzer. The Analyzer was calibrated before each 90-minute test period. See figures at the end of this report.

Comments:	Variations in 02% maybe due to the location of the patients moving closer or further away from the test point.

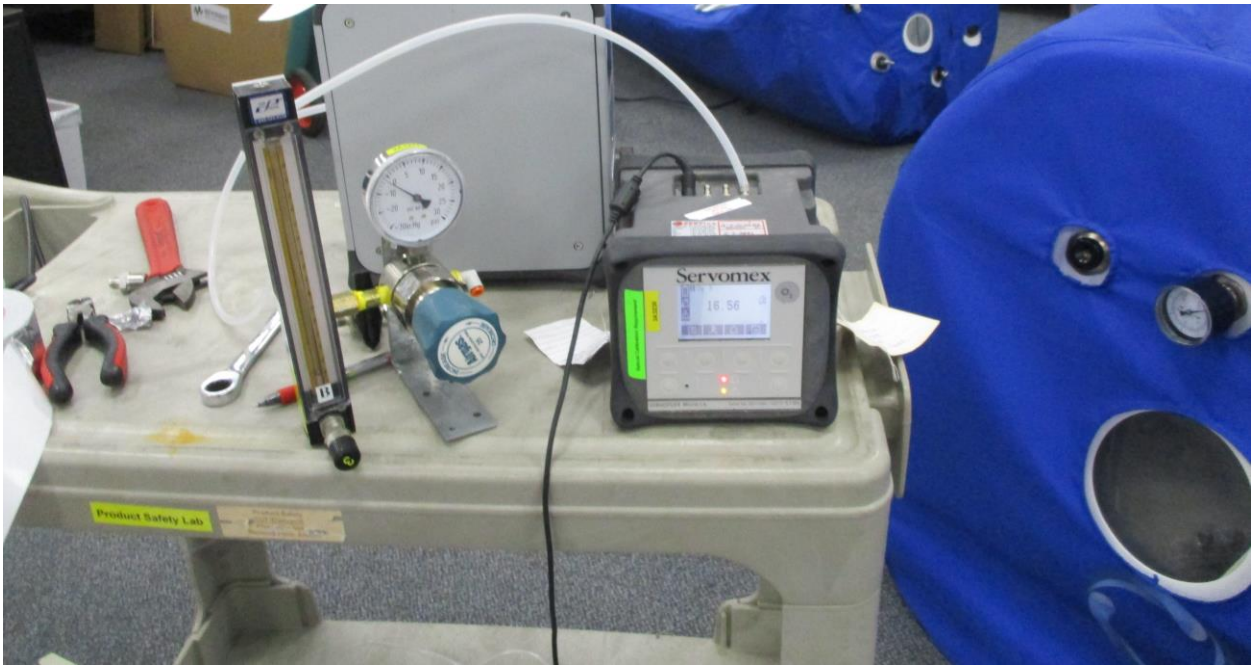
Asset #:	Item description:	Manufacturer Name:	Model #:	Cal. Date:	Cal. Due:
3A3118	Temperature, Humidity and Pressure Recorder	Omega	OM-CP-PRHTemp2000	10/22/2021	10/22/2022
3A3425	Stop Watch	SPER Scientific	810022	10/06/2021	10/06/2022
3A3230	02 Analyzer	Servomex	5100	FVBU	FVBU
-	Oxygen	Air Gas	19.97 %	COA	COA

Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		

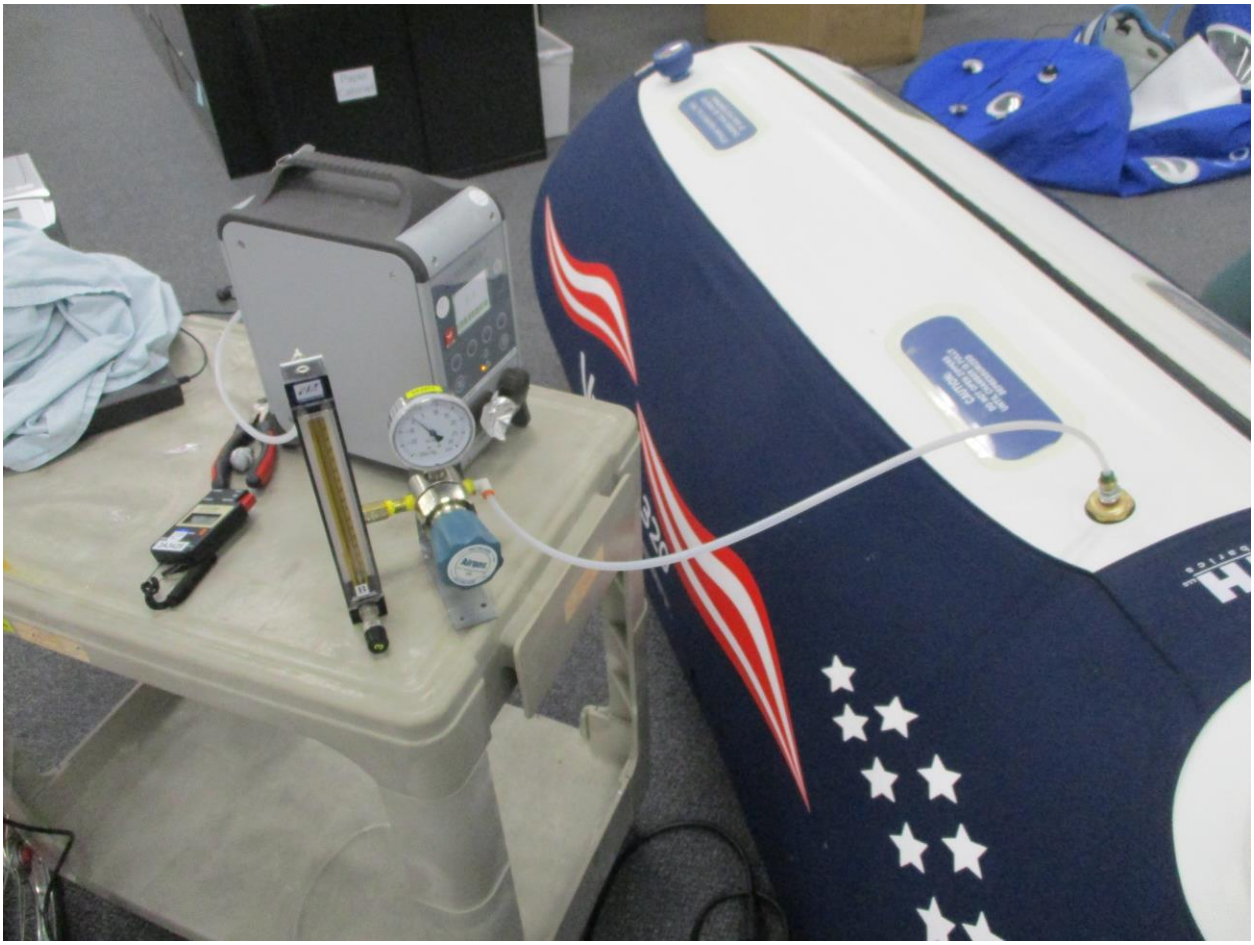
Input Supply Ratings:	-	V	-	A	-	Hz	-	AC	-	DC

Figures – Test Set-ups

Project #	115944						CEIT #	21916-1 thru 9			
Manufacturer:	-		Model #				OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.				
Product Description:	Mild Hyperbaric Chambers										
Input Supply Ratings:	-	V	-	A	-	Hz	-	AC	-	DC	



Project #	115944	CEIT #	21916-1 thru 9
Manufacturer:	-	Model #	OxyHealth Vitaeris 320 with AIRSEP Concentrator, Oxyflow Sitting Soft Chamber with Canta Concentrator Unit, Oxyflow Horizontal Soft Chamber with Canta Concentrator Unit.
Product Description:	Mild Hyperbaric Chambers		
Input Supply Ratings:	- V - A - Hz - AC - DC		



TENTATIVE INTERIM AMENDMENT BALLOT

EMERGENCY NATURE SELECTION OF RESPONSES

A. The standard contains an error or an omission that was overlooked during the regular revision process.

B. The NFPA Standard contains a conflict within the NFPA Standard or with another NFPA Standard.

C. The proposed TIA intends to correct a previously unknown existing hazard.

D. The proposed TIA intends to offer to the public a benefit that would lessen a recognized (known) hazard or ameliorate a continuing dangerous condition or situation.

E. The proposed TIA intends to accomplish a recognition of an advance in the art of safeguarding property or life where an alternative method is not in current use or is unavailable to the public.

F. The proposed TIA intends to correct a circumstance in which the revised NFPA Standard has resulted in an adverse impact on a product or method that was inadvertently overlooked in the total revision process or was without adequate technical (safety) justification for the action.