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MEMORANDUM

TO: Technical Committee on Hyperbaric and Hypobaric Facilities
FROM: Elena Liolin, *Senior Committee Administrator*
DATE: June 19, 2023
SUBJECT: NFPA 99 Proposed TIA No. 1735 **Circulation of TC Ballots**

The **initial ballot results** of the TC balloting on proposed TIA No. 1735 are as follows:

20 Eligible to Vote
6 Not Returned (*Chiffolleau, Dixit, Gustavson, Mize, Puchovsky, Ramos*)

Technical Merit:

0 Abstentions
0 Agree
14 Disagree (*Beal, Bell, Bryant, Burman, Charash, Cone, Garay, Garrett, Gresho, Hummel, Johnston, Mejia, Sheffield, Talati*)

Emergency Nature:

0 Abstentions
0 Agree
14 Disagree (*Beal, Bell, Bryant, Burman, Charash, Cone, Garay, Garrett, Gresho, Hummel, Johnston, Mejia, Sheffield, Talati*)

There are two criteria necessary to pass ballot [(1) affirmative $\frac{3}{4}$ vote and (2) simple majority] with both questions needing to pass ballot in order to recommend that the Standards Council issue this TIA.

Therefore, based on the responses received to date the initial ballot results show that this TIA **IS NOT** passing ballot.

During the circulation period you may change your vote or submit your ballot through the NFPA online ballot system at the following link: [NFPA Ballot Link](#).

Please complete the ballot on or before **June 26, 2023 by 11:59 p.m. ET.**

While completing your ballot, please remember the following:

- **A comment is required for both Question No. 1 and Question No. 2 for the online TIA ballot. Comments must accompany all Negative, Abstaining and Agree votes.**
- **If you vote “Agree” on Question 1, simply add “Agree” to the comment field and if you vote “Agree” on Question 2, insert the applicable letter(s) selections in the comment field which can be found in the Instructions box on the ballot site.**

You must hit SUBMIT to SAVE your work. **Note:** the system session will time you out after 45 minutes; any work not submitted at that time will not be saved! You may return to finish or change your ballot at any time up to the closing date. Ballot comments exceeding 4,000 characters must be submitted in a Word document via email, to Elena Liolin at eliolin@nfpa.org.

Note: Please remember that the return of ballots and attendance at committee meetings are required in accordance with the Regulations Governing the Development of NFPA Standards.

NFPA 99 (A2023) TIA Log No. 1735 - CIRCULATION REPORT

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 : 6

Milosh T. Puchovsky,Gwenael
Chiffolleau,Coleen Ramos,Ramesh K.
Dixit,Richard Bartlett Gustavson,Jeff
Mize

Vote Selection

AGREE

Votes Comments

0

DISAGREE

14

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.

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.

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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, aerospace 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.

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.

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 - CIRCULATION REPORT

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.

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?

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.

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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 is 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."

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.

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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.

ABSTAIN

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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 : 6

Milosh T. Puchovsky,Gwenael

Chiffolleau,Coleen Ramos,Ramesh K.

Dixit,Richard Bartlett Gustavson,Jeff

Mize

Vote Selection

Votes Comments

AGREE

0

DISAGREE

14

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.

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.

NFPA 99 (A2023) TIA Log No. 1735 - CIRCULATION REPORT

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.

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.

W. Robert Bryant

I do not believe that any of the six suggested responses are applicable

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.

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., & Bhattacharyya, 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>

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David Charash

The testing that has been done to date is not done by an independent body and is subject to bias. The rationale 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 of 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.

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.

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.

ABSTAIN

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