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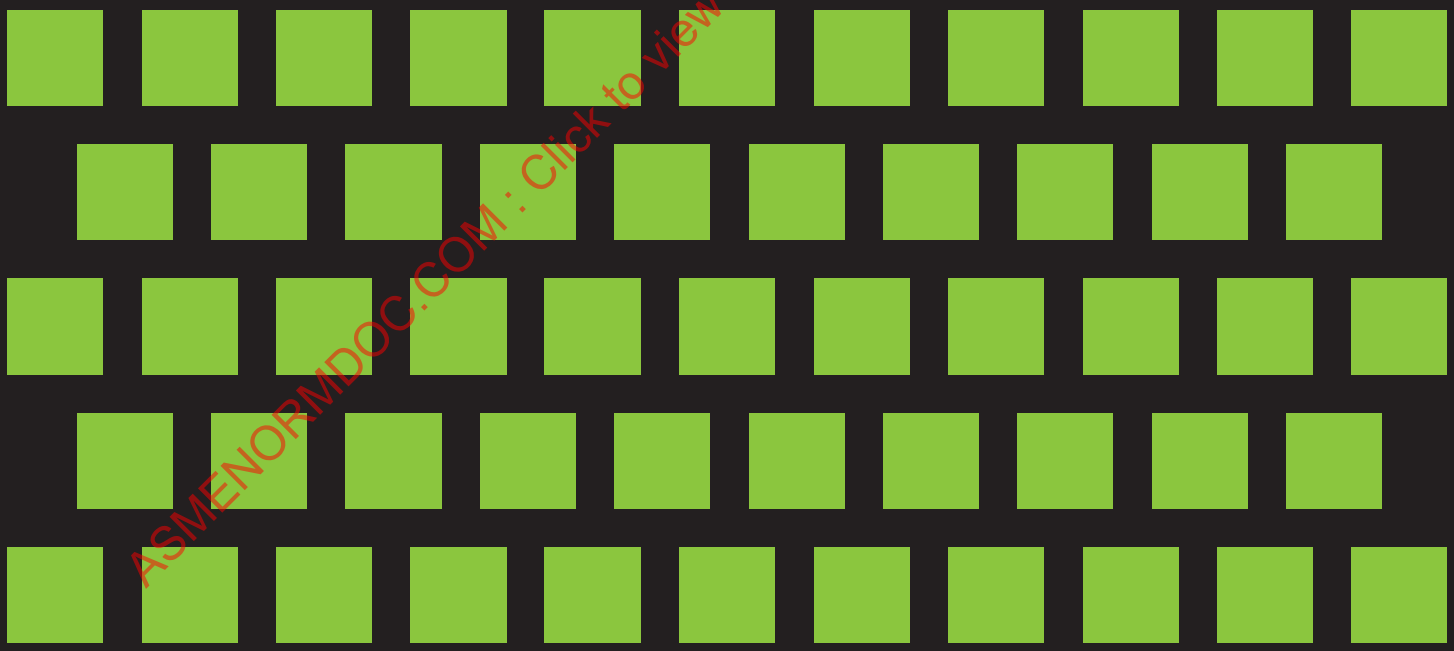
Principles of Safety and Performance for Medical Hyperbaric Chambers: Guidelines for Regulatory Submission



ASME STANDARDS TECHNOLOGY, LLC

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PRINCIPLES OF SAFETY AND PERFORMANCE FOR MEDICAL HYPERBARIC CHAMBERS: GUIDELINES FOR REGULATORY SUBMISSION

Prepared by:

ASME PVHO Subcommittee
on Medical Hyperbaric Systems

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FOREWORD

In the United States, Hyperbaric Oxygen Therapy (HBOT) is considered to be a medical treatment and requires a physician's prescription. Furthermore, Hyperbaric Chambers intended to be used to administer HBOT treatments require Federal Drug and Food Administration's (FDA) approval. Similar regulatory submissions such as the Global Harmonization Task Force (GHTF) document "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" are required in other countries.

This publication provides guidance for completing such regulatory submissions as well as principles of safety and performance of Pressure Vessels for Human Occupancy intended for use as medical devices. The FDA's regulatory submission package encourages compliance to the ASME PVHO-l Standard, and therefore compliance with the PVHO-l Standard requirements pertaining to the manufacture of Hyperbaric Chambers are recommended in this Guide.

The work contained in this publication was started in 2007 by the PVHO Subcommittee on Medical Hyperbaric Systems. The technical review was conducted by the ASME Pressure Vessel for Human Occupancy (PVHO) Committee over a period of three years. The PVHO Committee which conducted the technical review consists of twenty three members and two delegates representing several industry sectors which include manufacturers, users, insurance companies, regulatory and governmental agencies, as well as five countries: the USA, Canada, England, Germany and Australia.

Established in 1880, the American Society of Mechanical Engineers (ASME) is a professional not-for-profit organization with more than 127,000 members promoting the art, science and practice of mechanical and multidisciplinary engineering and allied sciences. ASME develops codes and standards that enhance public safety, and provides lifelong learning and technical exchange opportunities benefiting the engineering and technology community. Visit www.asme.org for more information.

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ABSTRACT

This document is intended to provide guidance with development, review and approval of regulatory submissions involving hyperbaric chambers. While there are specific standards and regulatory requirements for the design, production and regulatory approval of medical devices and pressure equipment, there has not been regulatory guidance for the evaluation of pressure vessels intended for use as medical devices. This document provides assistance for completing regulatory submissions such as the Global Harmonization Task Force (GHTF) document "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" and the United States Food and Drug Administration's (FDA) Premarket Notification process (510k).

1 SCOPE

This document applies to hyperbaric chambers intended for use as medical devices for the clinical treatment of various diseases and conditions. This document may also find application in related areas such as for hyperbaric chambers intended for medical research.

2 DEVICE DESCRIPTION

Hyperbaric oxygen (HBO_2) is a treatment in which a patient breathes oxygen while inside a hyperbaric chamber at a pressure greater than sea level pressure (i.e. >1 atmosphere absolute (ATA)). A hyperbaric chamber is a device intended to increase oxygen levels in a patient's tissue by means of pressurization to greater than atmospheric pressure. There are two basic chamber configurations: monoplace chambers intended to contain one occupant and multiplace chambers intended for more than one occupant. In the United States, hyperbaric chambers are prescription medical devices, to be purchased and used only under the direction and supervision of a licensed physician or practitioner in an appropriate healthcare facility.

The primary hazards associated with the use of hyperbaric chambers are: pressure boundary failure, with consequent rapid pressure loss and potential personnel injury; and fire, with consequent pressure rise, equipment damage and potential patient/attendant injury. These hazards must be considered in the governing standards and in the design of hyperbaric chambers.

Various types of chamber configurations are available in the marketplace, ranging from single occupant chambers manufactured from flexible composite materials that may also be capable of being folded and transported, to large steel chambers that can accommodate multiple patients along with medical attendants.

There are currently two basic types of monoplace chamber designs available: the all metal chamber with one or more windows and the acrylic cylinder chamber with metal ends. Monoplace chambers are in use throughout the world, primarily in hospitals and clinics. In recent years there has been considerable interest in chambers constructed of materials other than the metallic materials traditionally used.

The most prevalent type of monoplace chamber is the acrylic cylinder chamber, with a significant portion of the chamber body being comprised of a single acrylic cylinder, held in place by steel tie rods connecting two metallic end caps. The common element of the acrylic cylinder chamber is the patient's ability to view his surroundings which eases patient confinement anxiety and allows relatively unobstructed viewing and monitoring of the patient by attending medical personnel. One of the chamber end caps has a door mechanism to allow patient entry and egress. The patient entry/egress process is handled by a variety of door closure designs, ranging from interrupted breech rotating lock to a simple cam-action lever closure. All closures must meet the basic needs of safety under pressure and rapid opening capability.

Patients are placed in monoplace chambers through the use of gurney/stretcher systems or chair support systems that allow patients to be transported to, and placed into, the chamber, either reclining or in a semi-seated position.

Provisions are made in the chamber hull or door to allow connection of necessary HBO_2 qualified electrical equipment leads to connect external patient monitoring devices. Introduction of intravenous fluids to the patient during HBO_2 treatment is accomplished via pressure-capable pass-through devices in the door or chamber hull. Patient ventilation is also possible using a pressure capable pass-through or pass-throughs and a ventilator qualified for use in a hyperbaric chamber.

Monoplace chambers are usually pressurized with 100% oxygen but may be pressurized with medical breathing air at pressures up to 3 ATA. All chambers should have provisions for administering necessary gas to the patient by use of a mask or hood system, thus allowing prescribed air breaks during oxygen pressurization or inhalation of oxygen during the therapy cycle, if air pressurized.

Multiplace chambers are pressurized with compressed breathing air. Multiplace chambers are typically made from metal, in a cylindrical configuration. Rectangular and square configurations are

also available. Occupancy can range from two persons to twenty or more. Multiplace chambers have acrylic viewports and often additional pressure locks, allowing access to the chamber when pressurized.

Due to the more complex nature of a multiplace chamber, equipment and devices for patient monitoring or comfort may be installed inside the chamber pressure boundary, requiring that they be designed and validated for use in a pressurized environment.

Redundant air pressurization and filtration systems are necessary to support large multiplace chambers. Patients in a multiplace chamber breathe 100% oxygen through the use of a mask or hood system, with overboard exhaust of exhalation gases.

Multiplace chambers have seating facilities for multiple patients and attendants, and some have provisions for stretcher systems. They are normally fixed installations, due to the more elaborate pressurization and support equipment requirements. There are smaller multiplace design chambers that are transportable, such as deck decompression chambers used in the diving industry.

Fire suppression systems are required for multiplace chambers. Typically water deluge designs are used.

3 GENERAL SAFETY INFORMATION

Various health hazards are generally associated with the use of hyperbaric chambers as detailed in the table below. A detailed risk analysis should be performed to identify specific risks related to the identified hazards associated with the actual chamber as designed and constructed. All hazards should be identified and addressed in the risk analysis. The regulatory submission should describe the risk analysis method(s) utilized.

Table 1 - Example Hazards and Mitigation Table

Identified Hazard	Recommended mitigation measures
1. Pressure Related	Pressure Vessel conforms to ASME B&PV Code Section VIII Division 1 or 2, ASME PVHO-1 Standard, NFPA 99
2. Gas Embolism	Operate per Physician's Order
3. Oxygen Toxicity	Operate per Physician's Order
4. Confinement Anxiety	Adequate Patient Space and Visibility
5. Hyperthermia/Hypothermia	HBO_2 Suite Air Conditioning, Proper Patient Attire
6. Barotrauma	Responsive Pressurization/Depressurization Control System
7. Decompression Sickness	Operate per Physician's Order
8. Acoustic Trauma	Operate per Physician's Order
9. Electrical Malfunction	Intrinsic Safety Barriers, Fuses
10. Fire	Proper selection of Materials of Construction, Fire Suppression System, NFPA 99 conformance, Operating Procedures
11. Operator Error	Operation, Training and Qualification of Attendants
12. Patient Induced	Patient Intake and Preparation Procedures
13. Outside Event Related	Facility Conformance to Requirements of Jurisdiction Having Authority
14. Dangers of Patient Isolation	Adequate Patient Space and Visibility
15. Incapacitation of the Attendant(s)	Multiple Attendants, Patient Alert Capability
16.Electromagnetic Interference	Conform to IEC 60601-2
17. Software Control Malfunction	Fail Safe Systems, Visual and Audible Alarms

4 ESSENTIAL PRINCIPLES AND EVIDENCE OF CONFORMITY

4.1 Materials

4.1.1 Pressure Bearing Components

The selection of materials to be used for pressure bearing components of the hyperbaric chamber is critical to the safe use of the device. Pressure bearing materials should be selected based on their physical properties in relation to the pressures and temperatures at which they will be used. It is recommended that the material requirements of the ASME PVHO-l standard be met. Materials listed in Section VIII of the ASME Boiler and Pressure Vessel Code are presumed acceptable for use based on their properties. However, it should be noted that local regulatory requirements may include additional material properties and alternative material approval requirements.

It is recommended that manufacturers of chambers constructed of materials not specifically listed in the PVHO-l Standard, including non-metallic materials, submit a recommendation to ASME for a PVHO-l Case which, if approved, would provide criteria for acceptance of such materials.

Acrylic viewport windows and tubes shall be designed, fabricated and tested according to the latest edition of ASME PVHO-1.

4.1.2 Material Compatibility

Parts should be made from materials that are compatible with the gases and agents with which those components are designed to come into contact, and minimize health risks due to substances leached from the device in use. Oxygen compatibility must be considered.

4.1.3 Toxicity

No toxic materials from the hyperbaric chamber or its accessory devices should come in contact with the patient or operator during normal use. Non-toxic materials should be selected or potentially toxic materials tested to reduce the risk of exposure to toxic materials or vapors.

4.1.4 Biocompatibility

The designer should evaluate the biocompatibility of any materials in the chamber that could have direct contact with the patient and ensure that such materials will tolerate sterilization.

4.1.5 Sterility

Cleaning and disinfecting procedures and accepted materials should be specified in operation and maintenance instructions where applicable.

4.2 Specifications

The following information should be provided to the owner and user:

a. Rated number of occupants;

b. Maximum operating pressure;

c. Pressurization/depressurization rates and conditions under which those rates are to be maintained;

d. Ventilation rates and the conditions under which those rates are to be maintained;

e. Requirements affecting the amount of stored gas reserves;

f. Number of breathing gas outlets and their characteristics;

g. Temperature and humidity control requirements, if applicable;

h. Minimum and maximum operating and storage temperatures;

i. Fire suppression requirements as they apply;

j. Type(s) of breathing gas delivery systems;

k. Pressurization gas (air or oxygen);

l. The edition(s) of all codes and/or standards used in the development of the User Design Specification.

5 SUMMARY OF DESIGN VERIFICATION AND VALIDATION

5.1 Materials

5.1.1 Pressure Bearing Materials

Materials to be used for pressure bearing components should be selected based on material properties and the intended use. The use of PVHO-l listed materials is recommended. Design calculations or the results of experimental testing should be provided with the submission to the applicable regulatory agency or entity.

5.1.2 Biocompatibility

Materials that come into direct patient contact should be evaluated for biocompatibility according to recognized standards and local regulatory requirements. Test results should be supplied or referenced in the submission to the applicable regulatory agency or entity.

5.1.3 Toxicity

Potentially toxic materials that could come into contact with the patient or that have the potential to off-gas toxic fumes should be tested according to recognized standards and local regulatory requirements. Test results should be supplied or referenced in the submission to the applicable regulatory agency or entity.

5.1.4 Material Compatibility

Materials should be selected for their compatibility with one another and for normal use with any fluids or gases. Special consideration should be given to compatibility with oxygen. Acrylic window and light pipe components should be restricted from intentional contact with non-approved materials by warnings in operation and instruction manuals. Material selection information should be provided with the submission to the applicable regulatory agency or entity.

5.2 Electro-Mechanical Safety

Any hyperbaric chamber designed for a pressure differential of 2 psi or greater across the pressure boundary should meet the safety requirements of the appropriate section of the ASME B&PV Code and ASME PVHO-1. Chambers, fixed or mobile, intended for use in health care facilities should also comply with NFPA 99, Health Care Facilities, Chapter 20, Hyperbaric Facilities, regardless of its design pressure. The chamber should meet the electro-mechanical safety requirements of IEC 60601-1: Medical electrical equipment – part 1: General requirements for safety for Type BF equipment and IEC 60601-1 Collateral Standard: Safety requirements for medical electrical systems.

5.2.1 Performance Testing of Hyperbaric Oxygen Chambers

In characterizing the performance of the hyperbaric chamber, the following performance studies should be included in the submission:

5.2.2 Pressure Vessel

The pressure vessel should be constructed and tested in accordance with the ASME Boiler and Pressure Vessel Code, Sections II, V, IX, and VIII, Division 1 or Division 2; ASME Pressure Vessels for Human Occupancy PVHO-1. Pressure vessels, fixed or mobile, intended for use in health care facilities should also comply with the additional requirements of NFPA 99, Health Care Facilities, Chapter 20 – Hyperbaric Facilities.

Evidence of compliance with the appropriate section of the ASME B&PV Code and ASME PVHO-1 should be supplied with the submission.

Other international codes and standards may apply depending on the specific country in which the chamber is to be sold and used. Evidence of compliance with such codes and standards as are applicable to the pressure vessel should be supplied with the submission to the applicable regulatory agency or entity.

5.2.3 Pressurization / Depressurization System (Controls)

Hyperbaric chamber controls should meet the requirements of recognized standards where applicable. In the United States, NFPA 99, Health Care Facilities, Chapter 20, Hyperbaric Facilities provides such guidance.

5.2.4 Performance Criteria

The control system should allow the operator to precisely control the pressurization and depressurization process. Performance varies with chamber size and type, but consistent and repeatable operation is a minimum standard. Validation test results for the control function should be supplied or referenced in the submission.

5.2.5 Controls Protection

The controls of medical devices should be protected from inadvertent or unauthorized changes or adjustment. The means of protection should be such as to preclude their defeat by patients, or other unauthorized persons.

All controls which increase or decrease a function should be marked with a legible indication to inform the operator which action(s) is (are) required to increase/decrease the controlled function. Controls and their associated markings should be readily visible or legible. Controls should be identified with their associated markings.

For controls, movement upward, to the right, or in a clockwise direction should increase the control function. Movement downward, to the left, or a counterclockwise direction should decrease the control function. Rotary gas flow controls are exempt from this performance criterion.

5.2.6 Connector Protective Incompatibility

a. Device connectors, including those on wires and tubing, should be designed such that insertion into a receptacle other than the one into which they are intended to be inserted or into a receptacle using an improper orientation should not be possible.

b. Electrical connectors of a device (e.g., electrical lead wires) should include a mechanism to prevent connection of the patient to a power source that may cause excess current flow.

5.2.7 Medical Gas Connections

Connectors of chamber pressurization gas or cylinders of alternate breathing gas not already specified in relevant national standards such as Compressed Gas Association (CGA) C-9-1982 should be designed differently from the connectors specified for other medical gases.

5.2.8 Mechanical Safety

The physical construction of the chamber should:

a. not have any exposed sharp edges;

b. be mechanically stable in the intended position(s) of use; and

c. provide protection to the operator and patient from moving parts.

5.2.9 Mechanical Vibration and Shock Resistance

The chamber (i.e., the complete system suitable for its intended use) should withstand the mechanical shocks and vibrations expected in the environments of intended use as defined by the design criteria or relevant recognized standards, and should remain operational within its specification. The results of engineering analysis or testing to recognized standards should be supplied or referenced with the submission.

5.2.10 Fluid Spill Resistance

The chamber should be so constructed that it continues to operate within its specification after benign fluids have been dripped on the electrical components of the device. Therefore, those components of the device should meet the requirements for drip-proof equipment as specified in applicable recognized standards.

5.2.11 High and Low Temperature and Humidity

a. The chamber should operate within its design specification when operating in the specified environmental temperature and humidity ranges. Testing should be performed in accordance with applicable recognized standards. The results of environmental testing should be supplied or referenced in the submission.

b. The chamber should not be damaged and should remain operational within its design specification after storage in the maximum and minimum specified environmental temperature range. Validation test results should be supplied or referenced in the submission.

5.2.12 Surface Temperature

Temperature of surfaces of a device an operator can contact during operation should not exceed 122°F (50°C) in an ambient of 95°F (35°C). The temperature of surfaces that may come in contact with the patient should not exceed 106°F (41°C) in an ambient of 95°F (35°C). Any surface temperature exceeding 106°F (41°C) that may come in contact with the patient should be justified with a scientifically valid explanation and data should be provided which demonstrates that the safety of the patient is not compromised.

Acrylic windows shall not be subjected to temperatures exceeding their design temperature. Under no circumstances shall an acrylic window be exposed to temperatures exceeding 150°F (66°C) during operation; this includes localized temperatures resulting from placement of heaters or lighting.

5.2.13 Strangulation

Provision should be made in routing, retention devices, or other means to minimize the risk of strangulation of the patient by wires or tubing inside the chamber. This may also be accomplished by providing instructions for routing of patient wires and tubing in the device labeling.

5.3 Electrical

The chamber should meet the design and safety requirements of ASME PVHO-1 and the applicable sections of NFPA 99. The chamber should also meet the electrical safety requirements of IEC 60601-1: Medical electrical equipment – part 1: General requirements for safety for Type BF equipment and IEC 60601-1 Collateral Standard: Safety requirements for medical electrical systems. In addition, the

chamber should conform to additional local regulatory requirements which extend or supplement IEC 60601-1 and IEC 60601-1-1.

Electrical testing should be performed to recognized standards and local regulatory agency requirements as applicable. The following areas should be addressed in the regulatory submission.

a. Auxiliary Input/Output
b. AC Power Grounding and Polarity
c. DC Power Sources
d. Electromagnetic Compatibility
e. Electrostatic Discharge
f. Voltage Dips, Short Interruptions and Voltage Variations
g. Fast Transient Bursts
h. Conducted Electromagnetic Energy

5.4 Software

Software should be developed according to established software development and validation procedures. An overview of software development and validation activities should be included in the submission. Software validation results should be included or referenced in the submission.

5.5 Visual and Audible Indicators and Alarms

5.5.1 Power Indicators

The device should have visual power indicators complying with applicable recognized standards to indicate that the device is energized. Pneumatically operated systems should clearly indicate that pressure is present or absent. Indicators should be conspicuously located on the chamber or control panel.

5.5.2 Visual and Audible Alarms

The device should have visual and audible alarm indicators, as necessary, complying with applicable recognized standards. Visual alarm indicators should be conspicuously located on the chamber or control panel. Sound levels of audible alarms should be designed to be readily heard and identified over any ambient operational background noise. A description of the visual and audible alarms should be included in the operations manual and/or instructions for use. A description of the visual and audible alarms should be included in the submission.

6 CLINICAL EVIDENCE

Hyperbaric chambers employing new technology or indications for use may warrant a clinical evaluation in order to ensure that the particular device design is safe and effective for its intended use. In such cases, a clinical validation plan should be developed taking into consideration the issues discussed below.

Once the clinical validation study is complete, all documentation related to the study should be maintained in the technical design file in accordance with applicable regulatory requirements.

The clinical validation plan should be sufficiently detailed to enable responsible regulatory authority to access the safety and efficacy of the design/treatment. The regulatory agency may request additional information about aspects of the clinical plan, if it is not clear how the plan addresses identified risks, or if additional information is needed to assess the adequacy of the acceptance criteria. It is recommended that clinical validation plans should be discussed with the responsible regulatory agency prior to commencement of the clinical study.

The clinical validation plan should include the following elements:

a. Statistical hypothesis

b. Sample size, which should be adequate to permit reasonable confidence in the measure of all safety and effectiveness parameters.

c. Statistical method(s)

d. Detailed description of the protocol to be followed. The protocol should be designed as a prospective, randomized clinical trial which should lead to Level 1 clinical evidence

e. A sample of any case report form to be used for design validation.

7 LABELING

The following items are specific to labeling of this device class and should be included in the submission.

a. Labeling placed on the device or packaging;

b. Operators manuals and other instructions for use;

c. Marketing literature or user training instructions;

d. Installation and service instructions;

e. Instructions intended to be provided to the patients regarding any actions the patient is expected to perform.