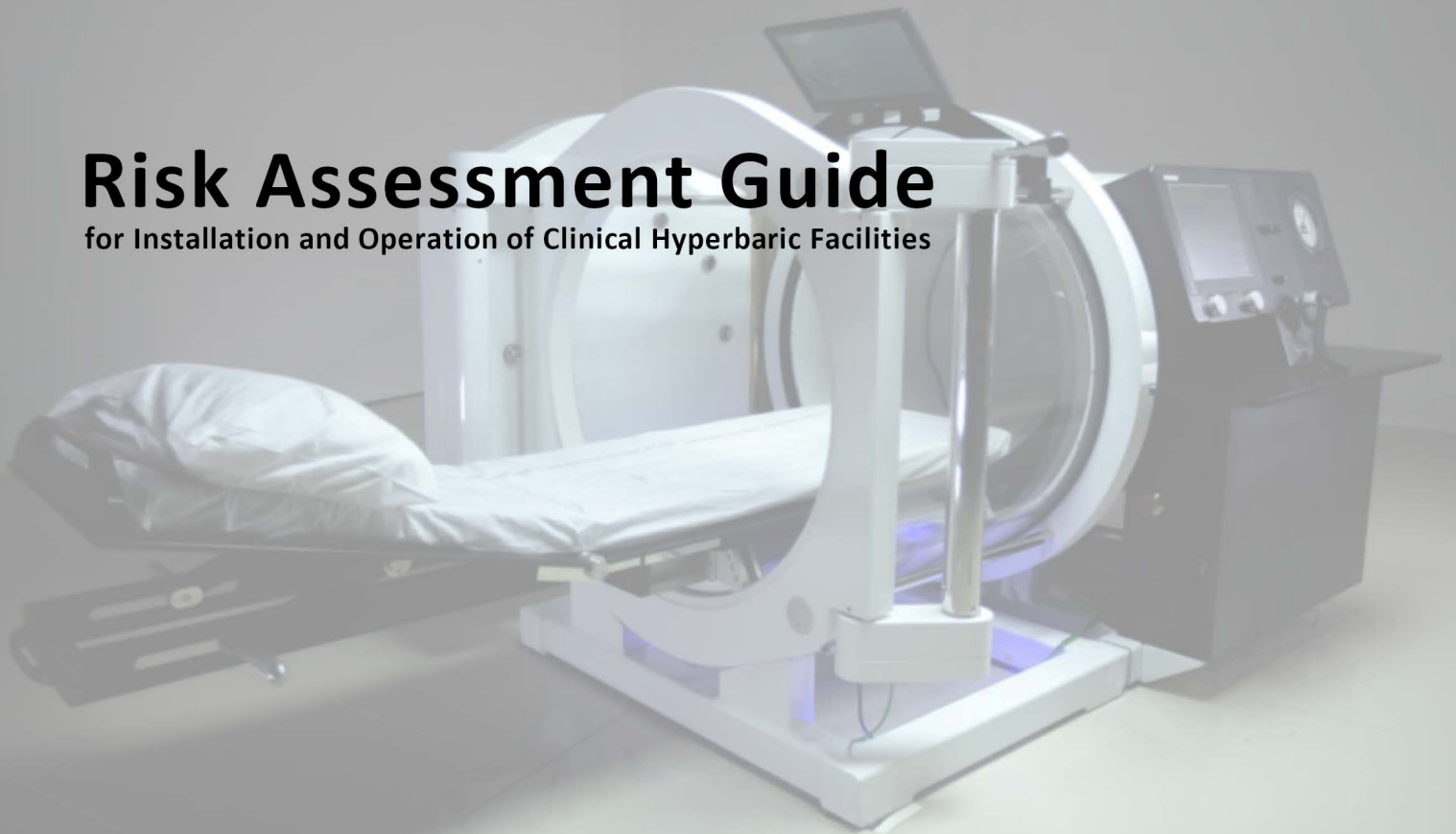


Risk Assessment Guide

for Installation and Operation of Clinical Hyperbaric Facilities



Francois Burman, Pr Eng, MSc

Risk Assessment Guide

For Installation and Operation of Clinical Hyperbaric Facilities

Sixth Edition

Section 1: Clinical Monoplace Hyperbaric Facilities

Section 2: Clinical Multiplace Hyperbaric Facilities

Francois Burman, Pr Eng, MSc

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Originally prepared for The Southern African Undersea and Hyperbaric Medical Association

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PREFACE TO THE SIXTH EDITION

Robert B. Sheffield, BA, CHT
Director of Education, International ATMO, Inc.
San Antonio, Texas

One of the challenges of risk assessment in a hyperbaric facility is weighing the relative importance and urgency of different potential risks we face. In my experience, newcomers to this field tend to view most hyperbaric hazards as equally risky. This is a natural reaction to a new hazard without a thorough understanding of its nature. With this mindset, risk assessment could be an overwhelming task.

The Risk Assessment Guide has always helped the reader understand the nature of hazards, making the process of risk assessment more manageable. However, the 6th edition of the Guide goes way beyond a mere update. New to the 6th edition is a scoring system based on the probability that a hazard will result in an accident, the severity of the possible accident, and the frequency of exposure to the hazard. This score ranks each type of risk; allowing the reader to prioritize risk prevention and risk reduction measures. The 6th edition of the Guide is a powerful tool for a hyperbaric safety program.

ROBERT B. SHEFFIELD, SAN ANTONIO, TEXAS USA 2019

PREFACE TO THE FIFTH EDITION

Robert B. Sheffield, BA, CHT
Chairman, NFPA Technical Committee on Hyperbaric and Hypobaric Facilities
Director of Education, International ATMO, Inc.
San Antonio, Texas

The Risk Assessment Guide is a valuable asset to the hyperbaric community. Mr. Burman has distilled his vast experience and expertise, gained through many years in engineering design, pressure vessel manufacture and physical assessments of more than 100 hyperbaric facilities around the world into a user-friendly guide to the potential risks we face in clinical hyperbaric facilities. The Guide is divided into two major sections - monoplace facilities and multiplace facilities. Each section is subdivided into smaller subject areas; and each subject is further subdivided into specific risk issues. Risk assessment is promoted through the format of the Guide. It is the process by which we explore the potential dangers inherent in our work. It is the basis for our codes and standards, and it allows us to understand the 'why' behind our existing rules. In this regard, the Guide is a useful tool in expanding one's hyperbaric safety knowledge.

Throughout the world, there is no single code, standard, or guideline that addresses all of the issues we face in a hyperbaric facility. The Risk Assessment Guide is one of the most comprehensive hyperbaric safety documents ever compiled. The Guide is an international document; and although it references standards from the United States and other countries, it focuses on the root issues (citing generally accepted standards where appropriate). It helps us understand and address all our safety issues, whether mandated by our local statutory requirements or not. It empowers the user to consider appropriate alternatives and address the necessary risk reduction measures. The Risk Assessment Guide is a practical tool in developing an effective safety program for a hyperbaric facility.

ROBERT B. SHEFFIELD, SAN ANTONIO, TEXAS USA 2010

PREFACE TO THE FOURTH EDITION

Kevin I. 'Kip' Posey, CHT
Manager & Safety Director
Nix Wound Care and Hyperbaric Medicine Center

From my involvement in hyperbaric training, I have seen increasing numbers of physicians, nurses, and technicians entering the field. Even though most health care professionals new to hyperbaric medicine have adequate medical education, their initial hyperbaric training alone can not adequately prepare them to assess all the risks associated with hyperbaric oxygen therapy. These risks are encountered throughout the entire life-cycle of a hyperbaric facility, from design through installation and operation. With new medical equipment and products available in ever increasing numbers, the future of hyperbaric medicine is certain to become more technologically advanced and complex. This will create an even greater need for appropriate risk management.

I have used this *Risk Assessment Guide* extensively as a hyperbaric safety director and educator. It is a primary reference and a must for safety directors. With each use I am reminded how user-friendly, informative, and comprehensive it is. Every member of the hyperbaric team from physician to technician can easily find useful information. It is structured to help you learn about hyperbaric safety issues. For each risk, you will find: classification (oxygen purity, textiles, grounding, etc), nature of the hazard, risk level (rating of importance/urgency from 1-4), and minimum requirements to mitigate the risk. It has value for the novice and the experienced person because it helps you understand the 'why' behind the safety issue. This may be the most important aspect of the *Guide*.

In my opinion, Francois Burman has created the best stand-alone tool available for hyperbaric risk assessment and mitigation. I recommend this book to any hyperbaric system installer or operator.

KEVIN I. POSEY, SAN ANTONIO, TEXAS USA 2006

PREFACE TO THIRD EDITION

Paul J. Sheffield, PhD, CASP, CHT
Chairman, UHMS Education Committee
President, International ATMO, Inc.

Like all other medical procedures, hyperbaric oxygen therapy is administered with a certain degree of risk. Recently, a few highly publicized international hyperbaric chamber incidents have heightened the concerns of healthcare professionals and raised the awareness levels of government officials and regulatory agencies. Thus, there is renewed emphasis on assessment of risk to the patient.

Healthcare professionals are highly educated in the benefits and the risks associated with application of hyperbaric oxygen. Unfortunately, their education contains very little emphasis on assessing other risks within the clinical hyperbaric facility. As a result, hyperbaricists usually have to educate themselves from various and sundry references. With the proliferation of clinical hyperbaric facilities outside the hospital setting, it has become increasingly important to consolidate the procedures for assessing relevant risks into a comprehensive safety guide.

Francois Burman, a Professional Engineer with considerable expertise in hyperbaric facilities, has provided healthcare professionals with the definitive document for assessing risk associated with installing and operating a clinical hyperbaric facility. Doctor Frans Cronje, President of the Southern African Undersea and Hyperbaric Medical Association and Medical Director of a wound care and hyperbaric medicine practice, has edited the work to ensure its clinical applicability. For convenience to the reader, separate Risk Assessment Guides are provided for both monoplace and multiplace hyperbaric facilities.

As a provider of continuing medical education, International ATMO, Inc is pleased to publish this 3rd edition of the Risk Assessment Guide. We consider it a valuable tool in our ongoing hyperbaric safety education effort to promote safe and effective application of hyperbaric oxygen therapy.

PAUL J. SHEFFIELD, SAN ANTONIO, TEXAS, USA 2002

PREFACE TO SECOND EDITION

W.T. Workman, MS, CHT
Director, Quality Assurance and Regulatory Affairs
Undersea and Hyperbaric Medical Society

The actual number of hyperbaric facilities in operation throughout the world is unknown. What is known however is that the role of hyperbaric oxygen in the treatment of a number of conditions is becoming more recognized throughout the international medical community. This has resulted recently in a dramatic increase in the number of treatment facilities available to the hyperbaric patient. Researchers from around the globe continue the pursuit to scientifically validate the role of hyperbaric oxygen in a number of exciting new applications. As scientists refine our knowledge of how high pressure oxygen may be beneficial in selected conditions, facility implementation is expected to keep pace with our increased knowledge.

There are many who will argue that the operation of a hyperbaric facility is rather simple and straightforward, and that its associated risks are benign. This could be no further from the truth. Yes, the operation of a hyperbaric chamber is relatively simple. Yes, the contraindications for the patient are few. Yes, the technology has been around for years. However, in order to effectively deal with those times when the situation is not a simple, cookie cutter event, one needs to fully comprehend the associated risks, recognize the hazards, prevent the untoward outcome if at all possible, and when not successful, then be competent enough to turn what would could be a potential mishap into a near-miss. As we witness the growth of hyperbaric medicine throughout the world, an in-depth understanding of the risks associated with its application is paramount in order to mitigate them.

When one thinks of the most dramatic mishap or accident that can occur in the hyperbaric environment, thoughts generally turn to fire. Though there have been several high profile hyperbaric fire mishaps in various parts of the world in recent years, the issue of fire is not the only safety issue that must be guarded against. In June 1999, a group of experts from the international hyperbaric medicine community met in Boston, Massachusetts to discuss whether there was a need for a standardized international hyperbaric fire safety standard. The United States, Europe, Latin America, the United Kingdom, Australia, and Japan were represented. Over the course of this two-day meeting, it became readily apparent to the group that perhaps what would be more beneficial than a consensus fire safety standard to the rapidly developing world of hyperbaric medicine would be a comprehensive risk assessment guide to assist those throughout the world with better understanding the safety element of hyperbaric medicine program and facility implementation. This conclusion was brought about, in part, from the group's realization that there is a general lack of knowledge of where the planner of a new hyperbaric facility can go to seek appropriate guidance to make sure the necessary safety elements are accounted for early into the planning process. Elements dealing not only with proper equipment selection and installation, but facility construction, ongoing operations, maintenance, medical staffing and training all need to be taken into consideration. Although the group recommended such a guide, it stopped short of producing it.

However, with the *Risk Assessment Guide for Installation and Operation of a Multiplace Hyperbaric Oxygen Therapy Facility*, Francois Burman has done just that. He has created a masterful resource document filling the void that exists in our knowledge base for a comprehensive guide to all elements of risks associated with hyperbaric facility installation and continuing operations. Mr. Burman's classical training as an engineer has given him the in-depth understanding of risk and the tools to produce a logical approach to risk management. His common sense approach provides responsible individuals not only the understanding to assess expected risks but the guidelines to meet those risks. There are numerous safety standards throughout the world dealing with various aspects of hyperbaric chambers and facilities. Mr. Burman has taken those standards and compiled them into a user-friendly resource that all can use and benefit from. I am convinced that the *Risk Assessment Guide for the Installation and Operation of a Multiplace Hyperbaric Oxygen Therapy Facility* will soon become a seminal document for the entire hyperbaric medicine community, regardless of country, state, region or city.

W.T. WORKMAN, SAN ANTONIO, TEXAS, USA 2001

PREFACE TO FIRST EDITION

Dr. C MacFarlane Hons. B.A., B.Sc (Hons), M.B.Ch.B., M.Med.(Surg), Ph.D., F.R.C.S.Ed., F.R.C.S.Eng.,
F.A.C.E.M(hon), F.F.A.E.M., M.R.A.C.M.A., D.M.C.C.
President, Southern African Undersea and Hyperbaric Medical Association

The practice of hyperbaric medicine in South Africa is growing, but is not universally present. Some of the more senior members of the profession are sceptical, remembering a time when hyperbaric therapy was used somewhat indiscriminately for dubious indications, and many of the younger members know little about it, not having been taught about it and never having had the availability of facilities. It is gratifying that those medical practitioners who use the facility regularly and in which the treatment is ethically, professionally and safely run are extremely satisfied with the results.

Lack of knowledge, failure of observation of international indications and standards, patient pressure and commercial considerations have resulted, unfortunately, in some hyperbaric practices occurring which are of questionable ethical status, and have worrying aspects of patient and chamber control. The results of this could impact negatively on hyperbaric practice in South Africa as a whole.

The Southern African Undersea and Hyperbaric Medical Association is a group of physicians with interest in and training in diving and hyperbaric medicine. Its committee structure also includes chamber technicians, paramedics, nurses, scientists, engineers and others, covering the full spectrum of activity. The association, as the largest group of such professionals in the country, sees itself as having an important role in the monitoring, auditing, regulations and safety of diving and hyperbaric medicine in South Africa, and is increasingly being recognised by statutory bodies as an authoritative and responsible authority in its areas of expertise. Guidelines have been developed in various areas, including credentialing of persons operating chambers for patient treatment.

A medical practitioner should refer patients for hyperbaric therapy, based on established indications, and should supervise all treatment. This implies knowledge, training and practice. A medical practitioner responsible for hyperbaric therapy is legally responsible for the equipment as well as clinical care and must ensure safety of the patient by utilizing safe, properly installed and operated chamber and equipment.

SAUHMA considered it important to provide safety guidelines to members and colleagues involved in hyperbaric practice, and through a technical advisory committee, commissioned the author to generate a comprehensive safety guide, taking both international and local safety factors into consideration.

The guide should equip the responsible medical practitioner with a quantitative means of ensuring that all the relevant risks associated with hyperbaric medicine are adequately addressed.

This Risk Assessment Guide is a most authoritative document, authored by an expert on behalf of the technical advisory committee of SAUHMA. It covers the field of practice well and provides a practical, usable tool, which should ensure that hyperbaric oxygen practice in South Africa is as safe as elsewhere. It is hoped that hyperbaric practitioners and facilities will avail themselves of the advice and guidelines contained, ensuring the safe and ethical practice of this invaluable, adjunctive medical treatment in South Africa.

On behalf of SAUHMA I wish to congratulate the author, Francois Burman, for making a major contribution to the safe practice of hyperbaric oxygen therapy and thereby promoting the well being of our patients. I would urge that all hyperbaric practitioners and facilities take cognisance of his excellent guidelines.

C. MACFARLANE, JOHANNESBURG, SOUTH AFRICA 1999

Section 1

Clinical Monoplace Hyperbaric Facilities

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Clinical Monoplace Hyperbaric Facilities

Scope

This Risk Assessment Guide is intended to apply to hyperbaric treatment facilities that are technically and operationally equipped to provide hyperbaric oxygen therapy (HBO). It addresses the various types of hazards associated with these facilities and details specific measures that need to be taken to contain the identified risks.

The scope of this guide is focused purely on the technical, operational, and safety aspects of monoplace HBO facilities. Medical decisions related to the treatment of patients remain subject to professional medical judgment and the availability of therapeutic resources.

Where the equipment in a hyperbaric facility has been specifically designed for this application and is fully compliant with the provisions of the relevant codes and standards, there should be no distinct hazard to human life, and no alterations to such equipment required. However, the safety factors relating to the environment in which such equipment is operated still need to be assessed.

Purpose

The primary purpose of this guide is to provide a means of assessing whether an existing facility complies with minimum safety requirements for the treatment of medical patients. It should enable the appointed safety representative to methodically and comprehensively assess the risks that a health care facility, HBO facility, operators and patients may be exposed to whilst being treated within a clinical hyperbaric facility and to remove, mitigate or minimise these risks.

In most instances, the Medical Director is legally responsible for the safety of the hyperbaric facility but may not be trained or competent in the appropriate safety issues. The guide is intended to provide the Medical Director with an objective means of ensuring that the hyperbaric facility, including additional or ancillary equipment, will be safe in accordance with reasonable occupational and technical principles.

In most instances, the Medical Director is legally responsible for the safety of the hyperbaric facility but may not be trained or competent in the appropriate safety issues. The guide is intended to provide the Medical Director with an objective means of ensuring that the hyperbaric facility, including additional or ancillary equipment, will be safe in accordance with reasonable occupational and technical principles.

In addition, it is also intended as a safety guide for the following purposes:

- to provide guidance in the acquisition of a new HBO facility; or
- to provide guidance for modifications or additions to an existing facility.

Basis

The basis for the compilation of this guide was a thorough analysis of the risks that are inherent to the following situations:

- the exposure of humans to hyperbaric pressures;
- the restrictive nature of hyperbaric chambers;
- the fire and explosion hazards associated with hyperbaric equipment;
- the multitude of associated mechanical and physiological hazards; and
- the hazards inherent in operating potentially dangerous machinery.

Each of these risks has been considered in the light of actual, quantifiable risks and of minimum measures required to mitigate, remove, or acceptably contain potentially hazardous situations.

Applicable Statutory Regulations and International Guidelines

The operation of pressure vessels for human occupancy, the operation of dangerous machinery, and general occupational health and safety provisions are commonly controlled by regional or national statutory or regulatory provisions. Neither this guide nor any other single document, code of practice, or set of operating instructions can supersede the requirement to comply with such provisions. All applicable statutes, regulations, standards, bylaws, and other regulatory instruments take legal precedence over the recommendations contained within this guide.

Many countries do not prescribe safety standards. This guide, originally commissioned by the Southern African Undersea and Hyperbaric Medical Association (SAUHMA), has been specifically compiled to facilitate safety assessments of hyperbaric treatment facilities that are located where safety standards are lacking – or as a supplement to applicable statutes and regulations.

This guide does not claim to comply either in part or in whole with any or all of these documents. Also, the listed documents typically apply to facilities that deliver a wide range of services and therapies, and only the issues and risks relevant to HBO treatment facilities have been considered here.

System Guidance Documents

- National Fire Protection Association (NFPA) *NFPA 99, Health Care Facilities*, 2018.
- Undersea and Hyperbaric Medical Society (UHMS), *Monoplace Hyperbaric Chamber Safety Guidelines*, 1997.

System Standards

- American Society of Mechanical Engineers (ASME) *PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy*, 2016.
- American Society of Mechanical Engineers (ASME) *PVHO-2, Safety Standard for Pressure Vessels for Human Occupancy: In-Service Guidelines (guidelines for PVHO acrylic windows)*, 2016.
- European Standard EN 12021:2014, Respiratory equipment. Compressed gases for breathing apparatus, 2014 (including November 2014 corrections).

Additional Guidance Documents

- American Society for Testing and Materials (ASTM) *G-93-96, Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments*, 1996.
- Australian Standards (AS) *4774.2-2002, Work in compressed air and hyperbaric facilities, Part 2: Hyperbaric oxygen facilities*, 2002.
- Compressed Gas Association (CGA) *G-7.1-2018, Commodity Specification for Air*, 7th edition, 2018.
- Compressed Gas Association (CGA) *G-4.1, Cleaning Equipment for Oxygen Service*, 7th edition, 2018.
- Compressed Gas Association (CGA) *P-45-2018, Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres*, 2nd edition, 2018.
- European Industrial Gases Association (EIGA) *33/18, Cleaning of Equipment for Oxygen Service*, 2018.
- National Fire Protection Association (NFPA) *70, National Electrical Code*, 2017.
- Naval Sea Systems Command, *US Navy Diving Manual, Revision 7*, 2017.

Readers Note: Specific attention has been devoted to fire safety, potentially the greatest threat to and most life-threatening risk within a hyperbaric facility. Thus, as far as is practical, the NFPA Guidelines have been applied. It is of importance to note that the NFPA 99 Standard is internationally recognised to have the most effective and lasting safety record, and represents the most comprehensive fire prevention standard in existence.

Explanation of Terms

The following key terms are defined in the context of this guide.

Class B Chamber - An air or oxygen environment, single occupancy or monoplace chamber.

Class 1 Division 1 - Implies a location in which ignitable concentrations of flammable vapours can exist under *normal operating conditions* or can exist *frequently due to leakage*.

Class 1 Division 2 - Implies a location in which flammable vapours are present, but in which these substances are normally confined within closed systems, or where ignitable concentrations of these substances are prevented by ventilation.

Competent - The use of the term “competent” as applicable to a person or authority throughout the context of this document, should, in all cases, be defined as a person or authority who is competent to perform or certify an activity, by virtue of their training, knowledge and experience, which is specifically applicable to the design, manufacture, testing, inspection, installation, management and/or operation of hyperbaric facilities or equipment.

Grounded - Connected to earth, generally to the body of the chamber, in order to provide a low-impedance return path for leakage and fault currents.

Intrinsically safe - Apparatus comprising electrical circuits in which any spark or thermal effect is incapable of causing ignition of a flammable mixture or combustible material in air.

Medical Director - A registered and suitably qualified medical practitioner, responsible for all medical activities and for the direction, quality, safety and service provided by the facility. This person is usually appointed in terms of occupational health and safety legislation as the “user” and therefore bears the overall responsibility for the facility under national legislation, or qualified designate, should be available throughout all treatments.

Oxygen-enriched - Any atmosphere, environment, or condition in which the concentration of oxygen exceeds 23.5% by volume.

Responsible - The use of the term ‘responsible’ as applicable to a person or authority throughout the context of this document, refers to a facility’s owner, manager, medical director or safety officer. In most countries, it is mandatory under occupational health and safety regulations to affect this appointment in writing.

Safety Officer - An appropriately qualified and *competent person*, delegated by the Medical Director and who is in charge of all equipment, operations, maintenance and safety-related matters, and authorised to control the access of equipment and supplies to the chamber within the facility. The term Safety Officer is synonymous with **Safety Director**, as used in some jurisdictions. This person should be involved in all aspects of planning, regulations and use of the facility.

Specialist - The term ‘specialist’ as used in this document should be assumed to include *competent persons*, professionally qualified experts (e.g., fire engineers or electrical or electronic engineers), and representatives of organizations recognized as specialists in a particular field.

Readers Note: A hyperbaric chamber environment is not classed as a Class 1 location due to oxygen-enriched concentrations. It is the possible introduction of flammable vapours (e.g., from alcohol swabs or medical dressings) into hyperbaric chambers, combined with the presence of sufficient combustible materials (including human skin) necessitates the specification of Class 1 requirements for the electrical systems, which potentially contain high-energy ignition sources.

Explanatory Notes

A risk is based on these three factors: 1) the probability that 2) an exposure to a hazard will result in 3) harmful consequences. The risk is higher where there is greater probability that an event will occur, greater frequency of exposure to a hazard, and/or greater severity of the consequences. Unless all three of these factors are present, no risk exists.

A *hazard*, by contrast, is a potentially harmful situation or agent. A *risk* results from exposure to a *hazard*.

The terms *hazard* and *risk* tend to be used interchangeably in many documents. In this document, however, *risk* refers to the probability of an adverse event, whereas *hazard* refers to the harmful situation itself.

The process of assessing risks associated with a monoplace hyperbaric oxygen treatment facility commences with a review of the impact of hazards associated with such facilities. The table below provides a description of each of the potential hazards and its associated risks.

Table 1: Nature of Hazards Applicable to Class B Monoplace Hyperbaric Chambers

Element	Description of Potential Hazards
<p>Fire and/or Explosion <i>Fire prevention within a Class B chamber is essential, as traditional extinguishment inside the oxygen-filled chamber is almost impossible.</i></p>	
<p>General description</p>	<p>Fire requires the presence of (1) a combustible or flammable material, (2) an oxidising environment, and (3) a source of ignition, either heat or energy.</p> <p>Under hyperbaric conditions, the reactivity of the oxidising environment is greatly increased, due to the increase in the partial pressure of the oxygen. This applies to air as well as to oxygen.</p> <p>In air-pressurised chambers, leakage of oxygen into the chamber environment due to improper or ineffective breathing apparatus sealing interfaces will dramatically increase the oxygen partial pressure.</p> <p>The flammability of materials increases as the partial pressure of oxygen increases, to the point where normally non-combustible materials may become flammable or combustible. Partial pressure of oxygen increases as chamber internal pressure increases, irrespective of whether the oxygen percentage also increases or not.</p> <p>Where the oxygen concentration exceeds 23.5% or more (defined as oxygen enriched atmosphere) at elevated total pressure, flame propagation increases rapidly. All survivable fires in hyperbaric chambers have occurred where the oxygen percentage was below 23.5%.</p> <p>The heat of combustion rapidly increases the local environmental pressure, causing the internal pressure within a hyperbaric chamber to exceed intended or safe working pressures.</p> <p>The results of a chamber fire thus include the depletion of oxygen in a breathing environment, the production of toxic gases and products, the combustion of human tissue, and the over-pressurisation of the pressure vessel.</p> <p>Much of this discussion on fire and explosion is equally valid for non-hyperbaric oxygen enriched situations and thus applies to any situation where oxygen concentration increases within a confined space.</p>
<p>Sources of fuel</p>	<p>The discussion is limited to materials generally not considered as sources of fuel, or where the combustion behaviour is dramatically different to that expected under normal circumstances. These include:</p> <p>Certain types of flame-resistant fabrics, silicone rubber, polyvinyl chloride, asbestos containing paint, glass fibre, polyamides, epoxy compounds, certain asbestos blankets and lubricants are all examples of materials that generally either require a high temperature for ignition, or do not combust in air at atmospheric pressure. These materials all burn vigorously in an oxygen-enriched environment.</p> <ul style="list-style-type: none"> • Flammable anaesthetizing compounds. • Human tissue, body hair, oils and fats that will burn readily in an oxygen-enriched environment. • Loose cotton garments, employed throughout hospitals that will ignite in 23% oxygen environments and will be totally destroyed in a 100% oxygen environment within 20 seconds.

Element	Description of Potential Hazards
Sources of fuel (cont.)	<ul style="list-style-type: none"> • Combustible fabrics “absorb” oxygen as the tiny air spaces become saturated with oxygen during treatments. Once removed to atmospheric air, these fabrics will burn (if ignited) almost as rapidly as if still within an oxygen environment. This hazard remains until sufficient time has elapsed for the oxygen to diffuse out and be replaced by air. • Oil-based or volatile cosmetics (facial creams, body oils, hair spray, etc.) all constitute a source of fuel.
Sources of ignition	<p>The following list is not exhaustive but illustrates several known sources of ignition: defective electrical equipment, high-voltage monitoring or radiological equipment, heated surfaces in broken vacuum tubes or lamps (even lamps used for illuminating diagnostic equipment and monitoring), hot-wire cautery or high-frequency electro-cautery, open or arcing switches, overheated motors, brushed motors, bare defibrillator paddles and electrical thermostats.</p> <p>The more obvious sources include: lighted matches or tobacco, static sparks from improper personal attire (manufactured using synthetic materials), non-compliant electrical wiring and oil-contaminated materials that present a spontaneous heating hazard.</p> <p>In oxygen-enriched environments, the minimum energy for ignition reduces greatly in relation to ambient air environments.</p>

Element	Description of Potential Hazards
Mechanical Hazards	
Potential energy	Even small volumes of compressed gas represent a large amount of potential energy. Should this energy be released suddenly, the effects on adjacent structures and personnel can be devastating. The release could be a result of failure of the vessel or the associated piping.
Deviation from code or standard	The above hazard may be created if the vessel is modified in a manner contrary to the original code or standard of design and construction.
Access	Any restriction on escape or impedance to rescue and firefighting efforts posed by the chamber create a hazard in case of an emergency.
Patient	In the event of a fire within the structure housing the chamber, a hazard exists to the patient inside the chamber. Inability to escape and loss of the chamber operator would pose a serious threat to the patient’s life.
Visibility	Reduction or restriction of vision of chamber operators reduces their effectiveness as safety monitors.
Sealed or semi-sealed containers	<p>Containers that may present hazards due to collapse or rupture during changes in pressures include ampoules, stoppered bottles, or capped bottles (e.g., multi-dose vials and glass intravenous infusion sets), air-filled cuffs used for breathing masks or positioning patients.</p> <p>Any air-filled containers taken into a chamber that are not adequately vented will either: collapse under pressure (possibly resulting in adiabatic heating of the contents and thus imposing a fire or explosion risk); or explode on resurfacing if the gas trapped within the container cannot escape during the ascent.</p>
Other hazards	Other mechanical hazards relate to the malfunction, disruption or inoperativeness of many standard items when placed in service under hyperbaric conditions. These also include the implosion of lamps and vacuum tubes (e.g., cathode ray tubes in medical monitors), overloading of fans due to a higher gas density, inaccurate operation of flow meters, pressure gauges and regulators.

Element	Description of Potential Hazards
Physiological Hazards <i>As stated under the scope of this assessment, medical considerations and complications are specifically excluded. The only hazards thus included under this section are those arising as a result of mechanical, electrical or other safety malfunctions.</i>	
General hazards	These include electric shock and the fouling of the atmosphere with carbon dioxide (CO ₂), carbon monoxide (CO), pyrolysis products from overheated materials, or toxic products generated during the combustion of materials (e.g., cyanide and chlorine).
CO ₂	Should the ventilation or air exchange system malfunction or be inadequate, CO ₂ levels could rise to toxic levels (due to the increased atmospheric pressure).
Rapid depressurisation	Rapid release of chamber pressure can lead to shock waves, noise and loss of visibility due to condensation of moisture in the chamber atmosphere. This may result where over-pressurization occurs, and the relief valve is activated.
Noise	During compression and subsequent ventilation, noise levels for the patient can be uncomfortably high.

Not all risks carry the same consequences or need for urgent attention. It is thus deemed prudent to use a risk level (RL) rating scale, as outlined in Table 2 below (and detailed in Appendix A).

Table 2: Risk Rating and Associated Requirements

RL	Risk Rating	Requirements
5	Very high	Attention and risk mitigation are critical and must be given highest priority. A potentially dangerous situation may exist, with the possibility of very serious or catastrophic consequences in the event of an adverse incident. Treatment activity should stop immediately and should not recommence until effective mitigation is in place.
4	High	Attention and risk mitigation are required and must be given high priority. A serious situation may exist that could endanger people or equipment or that could seriously disrupt or jeopardize the business. Solutions or actions that may mitigate the risk should be considered, at the discretion of the <i>Safety Officer</i> (see below for a definition of this term as used in this guide), and they should be recorded in writing.
3	Medium	Attention to the risk is required. Eventual exposure to this risk could likely result in an incident. Outcomes could include business disruption, financial or liability consequences, injuries, or equipment damage. Mitigation of the risk should be accomplished within practical time and cost considerations.
2	Low	Attention to the risk is recommended for the optimal functioning of the facility. Risk mitigation steps already in place should be recorded in writing.
1	Very low	The risk is acceptable. Note should be taken of the risk, but either it has already been suitably mitigated or its impact is of justifiably low significance.

However, risk levels may vary on a case by case basis, as a result of the following factors: 1) the type or nature of the facility; 2) the degree of qualified discretion allowed by national or local authorities; and 3) a determination by the Safety Officer of whether a risk is relevant.

During self-assessments by a facility, all risk levels 3, 4 and 5, as detailed in Table 2 above, should be addressed prior to regarding the facility as safe enough for regular operations.

The Risk Assessment Process

The following explanation illustrates one suggested method for applying this Guide in order to determine the degree of safety of a monoplace treatment facility. The process commences with an assessment of the applicable risks that affect a facility. The risks need to be identified as applicable, or as deemed appropriate by the Safety Officer. Guidance as to the importance of each classified risk is offered in the form of a risk level. The actual risk level may differ or be otherwise indicated by the *Safety Officer* as may be applicable in each case.

This is followed by a detailed physical evaluation of the facility in terms of its conformance to the relevant minimum requirements. It would be deemed appropriate for the facility's Safety Officer to describe in detail how each of the applicable minimum requirements has been complied with.

Where compliance with national or local regulations is stated, but where no such regulations exist, or are considered inappropriate for the facility, the Safety Officer should comply with the appropriate guideline detailed under the applicable statutory regulations and international guidelines listed above.

Where *specialist* advice suggests that exceptions to the minimum requirements are acceptable, these should be expressed in writing, together with all the motivating considerations, and presented to the owner or user for acceptance and endorsement.

In preparation for safety assessments or external review, this process should be undertaken in writing, specifically as it relates to the assessment of actual or likely risks and the compliance or non-compliance with the minimum applicable requirements.

This process should also be followed when any change in the status of equipment is anticipated, prior to equipment modification or prior to the acquisition of new equipment. A HBO treatment facility is an integrated unit, where even small changes to certain items may impact greatly on the overall operational safety.

Element: Chamber room lighting (typically a Risk Level 3)

Step 1: Identification of actual risk:

Ultraviolet light results in deterioration of chamber acrylic windows. Direct sunlight, mercury vapour discharge and certain types of fluorescent lighting are known sources of detrimental UV radiation.

Step 2: Application of minimum requirement(s) to address, remove or mitigate the risk:

Monoplace chamber windows should not be exposed to direct sunlight. Where fluorescent lighting is preferred, this lighting should be selected on the basis of an appropriate UV spectrum range (with only UV radiation with a wavelength above 320 nm being released at more than 30 cm (1 ft) from the lamp).

Comments:

All forms of fluorescent lighting, including the compact fluorescent lamp (CFL), produce UV radiation.

UV radiation is classified in 3 main ranges, based on wavelength in nanometers (nm):

UVA: $\pm 320 - 400$ nm: the least harmful, and almost negligible at distances of 30 cm (1 ft) and further.

UVB: $\pm 290 - 320$ nm: in sufficient quantities, causes sunburn and cancer. It also degrades acrylic windows.

UVC: $\pm 10 - 290$ nm: the most hazardous range to humans; typical used in germicidal applications.

The glass tubes used in incandescent, fluorescent and CFL lamps absorb almost all UV radiation. At distances greater than 30 cm (1ft), the amount of harmful UV light is negligible.

Metal vapour lamps, specifically metal halide and mercury lamps can produce sufficient UV light in the UVB range to degrade acrylic materials.

Where the minimum requirement cannot be met, the Safety Officer may exercise discretion by, for example, installing UV filters (covers, screens and films) between the source of UV radiation and the chamber acrylic window. In all cases, where such discretion is employed, this must be expressed in writing, endorsed by the owner or user, and preferably filed together with the completed compliance document.

Guidelines: Applicable Risks & Minimum Mitigation Requirements

1. Construction and Equipment				
Ref.	Element	Risks	RL	Minimum Requirements

1.1 Housing of Hyperbaric Facilities

1.1.1	Standards for Health Care Facilities	The risks associated with this hazard include fire safety, building safety, mechanical equipment safety, personnel safety, and operational safety.	3 3	a) National statutes, regulations, or standards and local bylaws or ordinances should be followed, especially as to fire safety and building and general facility matters. b) Chapter 14 of NFPA 99 (the National Fire Protection Association code pertaining to health care facilities) addresses all pertinent risks on a thoroughly integrated and comprehensive basis; it is specifically relevant to hyperbaric facilities and should be used for additional guidance.
1.1.2	Size of rooms housing the HBO chamber(s)	Inadequate room size presents accessibility risks during both routine and emergency situations, thereby compromising patient care and health.	3	Single monoplace chambers require a room at least 3.3 m wide by 7.2 m long (10 ft wide by 22 ft long). Dual monoplace chambers require a room at least 6.7 m wide by 7.2 m long (20 ft wide by 22 ft long).
1.1.3	Chamber orientation	Restrictions to egress from the chamber during emergencies could increase the minimum time to evacuate a patient.	4	Chamber orientation should allow immediate egress from the chamber, ease of patient transport as well as emergency evacuation.
1.1.4	Emergency configurations	Emergency extraction of patients.	4	Decompression and removal from a monoplace chamber should be achievable within 2 minutes.
1.1.5	Location (position) of operator	Where one operator is required to manage two chambers, impaired visibility could affect patient safety.	4	The operator should be located with the control panels for both units within sight and reach at all times. This may be achieved by mounting one of the chambers in the reverse direction, or by using a reverse-mounted control system for one of the chambers.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.6	Space for emergency procedures	Inadequate space to handle cardiac arrests, seizures or other patient medical complications could severely compromise the patient's health. Resuscitation equipment such as defibrillators may present an additional hazard where high oxygen concentrations are present.	3	All installations should be provided with adequate spaces for such emergencies. Where adequate resuscitation equipment is available in nearby locations in the hospital, these need not be provided within the HBO facility. For oxygen chambers, defibrillation and other electrical devices should not be used closer than 2 m (6 ft) from the open door of the chamber.
1.1.7	Exclusive use of rooms housing the HBO facility	Use of other, non-related hazardous equipment in a room housing a hyperbaric chamber could compromise the safety of the entire HBO facility.	3	Rooms housing HBO facilities should be for the exclusive use of the facility. Ancillary HBO equipment may be housed within these rooms.
1.1.8	Supporting foundations for the hyperbaric chamber	Inadequate supporting foundations could cause failure of the building support structures, especially during on-site hydrostatic testing. <i>Note: Monoplace chambers constructed primarily out of acrylic are not usually subjected to hydrostatic testing.</i>	4	All supporting foundations should be strong enough to support the chamber during all intended operations, preferably including hydrostatic pressure testing. This requirement may be reduced where the chamber could be removed for any future welding repairs or modification work, or where pneumatic pressure testing may be allowed under statutory requirements for the periodic testing.
1.1.9	Flooring	Non-conductive flooring may result in the build-up of a static charge on operator(s). The risk of this causing a fire outside the chamber is, however, considered to be low.	2	Conductive flooring is not mandatory for monoplace chamber treatment facilities as the discharge to ground will be an inconvenience rather than a safety issue. Some electronic devices may, however, be damaged when part of the path to ground.
1.1.10	Room temperature	Humidity and temperature control affect static electricity, as well as patient comfort and operator attentiveness.	3	Rooms housing monoplace chambers should be provided with air conditioning for compliant temperature and humidity control.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.11	External fire protection of facility rooms	A fire occurring outside of the HBO facility and endangering the patient and operator, presents an additional risk in that the patient cannot immediately be extracted from the chamber.	3	<p>HBO facility rooms should be of fire-resistant construction or should be offered sufficient protection from an outside fire to allow the patient to be surfaced (depressurised) and evacuated safely.</p> <p>All interconnecting doors should be rated as at least 1½ hour fire doors.</p> <p>A possible exclusion may apply to mobile or temporary facilities.</p> <p><i>Note: Mobile facilities are those where the chamber has specifically been designed and certified as a mobile or transportable portable unit.</i></p> <p><i>Temporary facilities are defined as those where the facility will be operated in a specified location for a maximum period of 3 months.</i></p> <p><i>However, and in all cases, exclusions should be subject to a site risk assessment, approval by the local fire protection authorities and should comply with whatever additional protective and safety measures have been deemed applicable by such authorities.</i></p>
1.1.12	Fire protection of rooms housing the chamber & ancillary equipment	<p>A fire in the chamber or equipment room may endanger:</p> <ul style="list-style-type: none"> a) the facility staff and patients, both inside and outside the chamber; b) the operators, preventing them from remaining at their posts during the required emergency termination and evacuation process; c) the chamber and ancillary equipment; d) the continued operation of ancillary equipment, preventing safe termination of the treatment; e) the remainder of the health care facility. 	3	<p>An automatic wet sprinkler system, designed and installed in accordance with local and/or national regulations pertaining to health care facilities, should be fitted in the chamber room, treatment areas, as well as in the ancillary equipment rooms.</p> <p>Mobile, temporary facilities and facilities housing chambers that are not fixed to the foundations are excluded from these requirements.</p> <p>Alternatively, where this is not deemed to be a requirement by local regulations, at least two portable fire extinguishers should be strategically located within the room.</p> <p><i>Note: Minimum national regulations take precedence although it remains a strong recommendation that a sprinkler system should be installed.</i></p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.13	Design & selection of room sprinkler heads	The sprinkler system must ensure sufficient time to bring the chamber back to atmospheric pressure and to evacuate the patients. The system must also prevent spreading of the fire to other parts of the health care facility.	3	National regulations that apply to both the number and type of sprinkler heads required for installation in health care facilities should be complied with. In addition, sprinkler heads should be equipped with low-rated fusible elements, offer a degree of direct protection to the chamber operator(s), and protect the chamber and ancillary equipment as much as possible. This clearly requires specialist advice.
1.1.14	Facility fire protection equipment	Failure of any fire suppression system control equipment jeopardizes the ability of the system to effectively extinguish a fire.	4	Quarterly visual inspections of fire-suppression system functioning components should be conducted. <i>Note: While fire alarm and deluge systems usually form part of a centralised department, or are performed by an external company, a hyperbaric facility has more restrictive evacuation options and careful attention to inspections, documentation and an even more frequent inspection schedule may be needed, based on the age and condition of the system.</i>
1.1.15	“No Smoking” signs	Any source of open flame presents a hazard in a location where the possibilities of high oxygen concentrations exist.	3	Signs prohibiting smoking should be clearly displayed both within and outside the HBO facility and a strict policy of no smoking should be enforced within the unit.
1.1.16	Lighting (UV)	Ultraviolet light results in deterioration of the chamber acrylic windows. Direct sunlight, mercury vapour discharge and certain types of fluorescent lighting are known sources of detrimental UV radiation.	3	Monoplace chambers should not be exposed to direct sunlight. Where fluorescent lighting is preferred, this lighting should be selected on the basis of an appropriate UV spectrum range (with wavelength above 320 nm).
1.1.17	Lighting	Flickering lighting may affect patients with higher flicker fusion thresholds, inducing eyestrain, headaches, fatigue and even seizures.	3	Controlled incandescent lights or dimmable fluorescent lighting fitted with electronic ballast (20 - 60 kHz frequency range) are suitable for use. All fluorescent lamps should be maintained and replaced appropriately.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.18	Telephonic communication	In the event of an emergency, the operator may not leave the HBO facility. Without an effective communication link with outside services, the operator would have to leave the control panel, losing contact and sight of the patient.	4	The HBO facility should be linked to the clinical alarm center by means of a telephone extension or intercommunication system, as well as a manual alarm activation device.
1.1.19	Cleanliness	Apart from health risks, greases, oils and dirt present additional fire hazards in areas where high oxygen concentrations may be present.	3	The HBO facility should be cleaned regularly to the satisfaction of the Medical Director.
1.1.20	Floor wax/polish	Commercial floor polishes and waxes often contain hydrocarbons (HC) and also impede conductivity with the floor.	3	Floors should not be coated with HC-based products that may be entrained into the chamber. Coatings should also not affect the conductivity of flooring.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.2 Design & Construction of Monoplace Hyperbaric Chamber

1.2.1	Design of Hyperbaric Chambers	<p>The utmost care must be taken in the initial design of a chamber, because once a unit is constructed and installed, structural changes to the pressure vessel are exceedingly difficult to carry out in complete safety.</p> <p>The use of inadequate, inappropriate, and/or unsuitable safety standards can compromise operator, patient, and/or facility safety; can compromise the safety of the entire health-care facility; and can result in noncompliance with relevant statutes and regulations.</p> <p>Pressure vessels are classified as hazardous equipment.</p>	<p>3</p> <p>3</p> <p>4</p>	<p>a) During the design of a chamber, all aspects of the chamber’s operation relevant to its intended use should be considered – e.g., internal size, layout, number of occupants, storage shelves and bracketry, and maximum working pressure.</p> <p>It is recommended that chambers be rated to a working pressure of at least 3 ATA (29 psig).</p> <p>b) Chambers should be designed to meet the requirements of any of the internationally accepted and applicable safety standards, as well as any relevant national statutes or regulations.</p> <p>Care should be taken to ensure that the selected standards are applicable to pressure vessels for human occupancy (especially with regard to viewport design). The ASME PVHO-1 (American Society of Mechanical Engineers’ Pressure Vessels for Human Occupation) standard, which dovetails with NFPA regulations, is the preferred standard.</p> <p>c) In addition, an internationally accepted life-support standard should be used to determine requirements for chamber equipment, ancillary equipment, levels of redundancy, safety system equipment, and maintenance, all as applicable to the intended use of the chamber.</p> <p>Examples of such standards include AS/NZS 2299, ABS, and LR.</p>
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1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.2	Approved treatment chambers	The use of pressurized equipment and the exposure of materials to high oxygen concentrations and pressures are associated with a range of mechanical, fire and physiological hazards. Insurance risks and statutory compliance risks are also relevant.	4	The requirements of the appropriate safety standard, international guidelines for vessels for human occupancy, legal statutes and insurance companies should be addressed. Compliance should be demonstrated through certification by an approved inspection authority. Chambers need to be permanently, legibly and conspicuously marked as being approved for: <ul style="list-style-type: none"> • air-filled only; • oxygen-filled only; or • air & oxygen filled. A copy of the original certification document should be retained at the facility.
1.2.3	Internal surface treatment or finish of chamber	Finishes that are chemically unstable, flammable, or otherwise unsuitable in a pressurized environment present both health and fire risks.	3	The interior of a chamber should either be untreated (e.g., if it is made of stainless steel) or be treated with a nontoxic, corrosion-inhibiting, low-flammability paint that is suitable for human occupancy and hyperbaric pressure applications.
1.2.4	Paint fumes	Initial off gassing of curing painted surfaces can present a health hazard.	4	No chamber should be used within the first 72 hours after application of an internal surface treatment, unless otherwise specified in the relevant material safety data information issued by the paint manufacturer.
1.2.5	Sound deadening materials	Certain sound deadening materials present a risk of fire.	3	If sound-deadening materials are used within a chamber, such materials should be flame-resistant.
1.2.6	Sufficient number of viewing ports & access ports for equipment	Inadequate allowance for visibility and access during the initial design and manufacture of a chamber may result in impaired ability to observe patients and/or may compromise the safe installation of monitoring and treatment equipment.	3 2	a) The initial design of the chamber should include a sufficient number of viewports and equipment access ports for piping, equipment and monitoring leads. b) A suitable guide is to allow for at least 50% excess capacity of access ports or penetrations.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.7	Viewport design	The design and maintenance of viewports are critical to safety and yet fall outside the scope of many international design and construction codes.	3 3	a) Viewports should be designed to meet the requirements of a safety standard that makes specific provision for nonmetallic, pressure-bearing structures. b) The service-life requirements, as defined by the safety standard should be adhered to. ASME PVHO-2 allows for an extension based on visual inspection by a <i>competent person</i> for use in a protected service environment.
1.2.8	Location of penetrations	Acrylic windows generally do not make allowance for any form of pressure bearing penetration. Penetrations form part of the pressure bearing envelope and any unauthorised modifications, alterations or new installations will directly affect chamber safety.	3	No acrylic windows should be modified from the original design and construction. Where penetrations are required to pass through an acrylic window, strict compliance with the safety standard using in the design and construction should be ensured. Penetrations should conform to the safety standard employed in the design and construction of the chamber. Additional penetrations, if and when required, should only be installed after specific review, approval and certification by the approved inspection authority.
1.2.9	Protection and care of acrylic windows	Acrylic is easily scratched and/or damaged by certain forms of radiation, impact and/or inappropriate cleaning solutions. Certain cleaning fluids and UVB or UVC radiation may cause viewport deterioration. This may result in obscured vision, or damaged that reduces life span.	3 3 3	a) Outer protective shields may be considered to limit mechanical damage to the inner, pressure bearing window. b) Acrylic windows should not be exposed to direct sunlight or any other source of UVB or UVC radiation, or to any direct source of heat. c) Care should be exercised to ensure that correct cleaning solutions and procedures are enforced. The ASME PVHO-2 standard provides guidance on the care and use of acrylic viewports.
1.2.10	Weatherproofing of electrical access ports	If access ports and electrical penetrators have not been adequately weatherproofed, there may be a risk of electrical shock, short-circuiting or equipment damage during activation of an internal or external deluge system and/or during cleaning.	4	All electrical circuits should be housed in weatherproofed enclosures capable of withstanding a deluge from the fire protection system, the application of cleaning solutions, and/or any precipitation to which the chamber might be exposed.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.11	Door seals	Any damage to a door seal may result in chamber gas escaping under pressure, introducing a high oxygen concentration hazard into the surrounding area.	2	<p>Chamber door (O-ring or lipseals) seals should be easily repairable or capable of operating safely with minor damage.</p> <p>Operators should be trained to identify leaks at door seals and to inspect the seal integrity before and after treatments.</p> <p>Spare seals should be maintained in the facility.</p>
1.2.12	Pressure-relief provisions	<p>Overpressurization of a chamber can result in a risk of mechanical damage or fire. Malfunctioning relief valves can compromise the safety of a chamber's patients.</p> <p>An excessively high set pressure may place the patient in danger from oxygen toxicity, nitrogen loading and rapid depressurization when the safety valve opens.</p> <p>Inadequate venting capacity of relief valves is a hazard that can lead to overpressurization.</p> <p>Venting from safety valves, either during testing or during actual operations may introduce oxygen-enriched gas into potentially hazardous areas (heat and/or electrical ignition sources).</p>	<p>5</p> <p>3</p> <p>5</p> <p>3</p> <p>3</p> <p>3</p> <p>4</p> <p>4</p> <p>3</p>	<p>a) Chambers should be fitted with an over-pressure safety valve, designed and tested under regular inspection authority survey, to prevent the chamber pressure from exceeding the vessel design pressure.</p> <p>b) Consideration should be given to specifying a set pressure of no more than 15% above the maximum operational working (treatment) pressure.</p> <p>c) Safety valves should be designed to be fully open at no more than 3% above set pressure.</p> <p>d) The reseal pressure limit should be no lower than 7% below the set pressure, and this function should be tested regularly.</p> <p>e) Relief valves should be fitted with external isolating valves to allow for shutting off in the event of malfunctioning.</p> <p>f) Valve handles should be wired in the open position using breakable safety wire.</p> <p>g) Internal ports should not be blocked or obstructed in any way other than with a suitable anti-suction device.</p> <p>h) Safety relief valves should be sized such that no situation can exist whereby gas can be introduced faster than can be discharged.</p> <p>i) In the case of oxygen-filled monoplace chambers, the discharge from the safety valve(s) should be connected to an exhaust line piped into a safe open space (i.e., not terminating near any heat or ignition sources, or hazardous areas). (Ref. also 1.4.26.)</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.13	Chamber pressure (life-support) gauges	<p>Not all gauges are of suitable repeatability and accuracy. This could detrimentally affect the quality of treatments as well as the safety of patients.</p> <p>If gauges are incorrectly installed, controlled, and/or maintained, they may not function accurately or effectively.</p>	<p>4</p> <p>3</p> <p>3</p> <p>4</p> <p>3</p> <p>3</p> <p>3</p>	<p>a) All chamber compartments should be fitted with an independent pressure gauge that can be read by the operator. This is usually achieved by mounting the gauge on the control panel.</p> <p>b) All gauges should be accurate and repeatable, should have scales appropriate for the expected pressure range, should be of a size suitable for easy readability (i.e., no smaller than 150 mm [6 inches] in diameter), and should be precise to a degree medically appropriate for measuring treatment pressures.</p> <p>An accuracy of $\pm 0.5\%$ of the gauge's full scale, or better, is sufficient for chambers with treatment pressures under 3 ATA. As chamber pressure may vary between zero and full scale, a life-support gauge requires accuracy over the full range.</p> <p>c) Pressure gauge lines should not supply any other devices.</p> <p>d) Internal ports for gauge lines should be protected with a shield to prevent inadvertent blockage.</p> <p>e) All systems should be correctly cleaned prior to use, and regularly checked for leaks.</p> <p>f) Gauges should be tested over the full treatment range at least once a year to ensure accuracy.</p> <p>g) In the event of any doubt, of gauge indicators that appear to be sticking, of mechanical damage, or if specified by the manufacturer, gauges should be retested more frequently than annually.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.14	Indicating pressure gauges	<p>Gauges used to indicate pressure in a line, vessel or on a pressure regulator do not require significant accuracy.</p> <p>However, in the event that these are non-functional (e.g., stuck in position), it would not be possible to observe pressure in the line.</p> <p>During setting up and shutting down chamber facility, or when opening any line or vessel for maintenance, failure could endanger the piping systems, vessels, and/or any maintenance staff.</p>	<p>3</p> <p>3</p>	<p>Pressure gauges should be sized so as to make reading easy, with a scale selected whereby the expected (normal) reading lies within the $\frac{1}{3}^{\text{rd}}$ to $\frac{2}{3}^{\text{rds}}$ of the full scale.</p> <p>The function of such gauges, should be regularly checked, i.e., during shut-down - for a zero reading, and when pressure is applied - for a reading at the expected level.</p>
1.2.15	Materials	<p>Fibreglass contains bonding agents that deteriorate with time, providing a source of highly combustible materials.</p>	4	<p>Fibreglass should be avoided for use within a Class B chamber.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.3 Illumination

1.3.1	Location & design of lighting	Lighting fixtures not designed for hyperbaric applications present serious explosion, implosion and fire hazards. In addition, regular maintenance and inspection activities are more complex.	3	Preferred location for the mounting of chamber lighting is on the outside. However, lighting designed to be pressure-proof, or pressure-compensatory and explosion-proof, and certified by a competent design authority as suitable for internal use, may be considered.
1.3.2	Temperature of external lighting fixtures	If external lights are used in conjunction with viewports, excessive surface temperatures can compromise the integrity of the viewport or viewport lens material.	4	Lighting fixtures should be designed in accordance with the requirements of a suitable standard that includes provisions regarding viewports. The temperature rating of the specific viewport material should be considered during the design of fixtures.
1.3.3	Emergency lighting	An illumination failure in a chamber without adequate backup lighting can lead to risks for both patients and medical personnel. In addition, any emergency responders will be hampered in their ability to act, leading to additional risks.	3 3 3	<p>a) Chambers should be fitted with sufficient lighting fixtures so as to provide suitable redundancy in the event of single failures.</p> <p>b) If a chamber has sufficient viewports, external room lighting may be sufficient to provide backup illumination.</p> <p>c) In addition, lighting power circuits should be connected to the chamber or health care facility's emergency power supply.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.4 Gas Supply Systems, Ventilation and Chamber Air Conditioning

Chamber Air Supply System Requirements				
	<i>Note: Some monoplace chambers are compressed with air, or have a gas switching capability (oxygen to air).</i>			
1.4.1	Air pressurization system	Insufficient air capacity for nonroutine or emergency treatments can compromise patient care during inadvertent power breaks that affect the compressor.	5	a) Air compressors and storage vessels should be designed with sufficient capacity to complete a maximum-duration medical treatment, including pressurization, and to supply the maximum, continuous ventilation demand.
		Excessive moisture can affect the ability of filtration systems to work effectively.	3	b) Compressed air systems should be fitted with after-coolers to ensure that excess condensate is removed prior to storage.
		Condensed moisture can also influence control valves and result in accelerated corrosion in storage vessels.	3	c) Compressors should be fitted with inlet filters capable of removing airborne particles larger than 10 µm in size.
		In addition, environmental particulates above a certain size can result in damage to the compressor's gas flow path	3	d) It is recommended that automatic drains be fitted to all filter housings.
1.4.2	Sources of air for a chamber	Toxic, flammable, or fouled air can be introduced into a chamber's air source by means that may be beyond the control of the facility's owner or manager.	5	a) Compressor intakes should be located so that toxic, flammable, or fouled air cannot be introduced into a chamber's system. Typical sources of fouling include vehicular activity, internal combustion engines, other mechanical equipment, and building exhaust outlets.
			3	b) Warning signs should be posted at the locations of all compressor intakes.
1.4.3	Handling of air for a chamber	Unsuitable or malfunctioning air-handling equipment can contaminate the air supply to a chamber. Contamination with oil or other hydrocarbons (HCs) presents a particular hazard in oxygen-enriched environments.	4	The air supplied to a chamber should be monitored as detailed in section 1.7.9. Efforts should be made to ensure that all known causes of contamination are eliminated by following correct maintenance procedures and by conducting regular inspections of compressor seals, air purification devices, and compressor intakes and filters.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.4.4	Compressor air intake	<p>Inappropriately located and/or inadequately sized air-intake piping can lead to excessive air intake resistance or a starving of the compressor.</p> <p>This may result in reduced air output and pressure, overheating, excessive oil consumption, and damage to the compressor.</p>	<p>3</p> <p>3</p>	<p>a) The introduction of any form of resistance to the flow of air, including remote location of a modified inlet filtration system without instruction or approval from the compressor manufacturer, should be avoided.</p> <p>As a general rule these criteria should be followed:</p> <ul style="list-style-type: none"> • The internal diameter of an intake hose should be increased by at least 6.35 mm (¼") for each 3 meters (10 feet) of extension, applied to the complete length of the hose; • If 90-degree bends or other similar flow restrictions need to be used, the internal diameter of the complete intake hose should be increased by 6.35 mm (¼") for each bend; and no more than 4 bends are recommended; • Provision should be made at the connection to the existing compressor intake to drain any condensate that might accumulate in the hose and run into the compressor intake; • The inlet to the extension hose should be covered with mesh to prevent insects or debris from being drawn in, and the opening should also face downward to avoid any direct rain from entering the hose; • The use of any form of filter at the inlet to the extended hose should be avoided; • The manufacturer's requirements and recommendations, if available, always take precedence. <p>b) Any extension of an intake hose should account for the added flow resistance.</p>
1.4.5	Use of oil-lubricated compressors	<p>If a chamber is served by an oil-lubricated compressor, a failure of the air-treatment package, inadequate maintenance procedures, or a failure of the compressor system could introduce oil and/or other HCs into the chamber's air supply. This presents a major risk of fire, especially in an oxygen-enriched environment.</p>	<p>3</p> <p>3</p>	<p>a) If a chamber is served by an oil-lubricated compressor, it should be fitted with an air-treatment package specifically designed to produce breathing air (ref. 1.7.9).</p> <p>b) Air-treatment packages on oil-lubricated compressors should be fitted with automatic safeguards to ensure either that contamination cannot occur or, if it does, that the air-supply system will shut down before the contamination can reach the chamber.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Use of an oil-lubricated compressor (cont.)		3	c) Oil-lubricated compressors and associated air-treatment packages should be diligently monitored and maintained.
1.4.6	Redundant air-supply capabilities	A failure of a chamber's air-supply system, especially during a life-threatening emergency treatment, can seriously compromise the patient's condition and the efficacy of the treatment.	3	<p>a) Air-supply facilities should consist of two or more individual systems, each with sufficient capacity to maintain the required flow rates on a continuous basis.</p> <p>This requirement may be met by using one large compressor, typically with a low-pressure rating, and one standby compressor, typically with a high pressure (HP) rating, which can be used to fill an adequately sized HP storage tank.</p> <p>Other acceptable options include two low-pressure compressors; two suitably sized HP compressors; or a large supply of stored air.</p>
			4	<p>b) At least one system should meet the pressurization and ventilation requirements of the full duration of any intended treatments.</p> <p>The standby system should meet the requirements of the full duration of the longest table used for life-threatening treatments (for example, the extended USN TT 6 [U.S. Navy Treatment Table 6]).</p>
			3	c) Each compressor should be supplied from a separate electric branch circuit.
1.4.7	Gas quality	<p>Unknown or non-certified gases may introduce flammable or combustible compounds into the chamber.</p> <p>Calcite crystals are known by-products of water-based lubricants used in certain oil-free (Teflon ring) gas compressors.</p> <p>In addition, environmental particulates above a certain size can result in damage to the compressor's gas flow path.</p>	4	HC and 5 µm particulate in-line filters should be used to remove contamination - preferably 1 µm filters where non-certified or suspect gas supplies are provided, from air, oxygen and gas mixtures.

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.8	Gas moisture content	Excessive moisture affects the ability of most filtration systems to work effectively. Condensed moisture can also influence control valves, and result in accelerated corrosion in storage vessels.	4	Compressed air systems should be fitted with after-coolers to ensure that excess condensate is removed prior to storage. It is recommended that automatic drains be fitted to all filter housings.
Chamber Oxygen Supply System Requirements				
1.4.9	Oxygen supply volumetric or capacity considerations	Correct volumetric considerations are essential for effective treatment as well as preserving the health care facility's other requirements.	4 4 4 3	<p>Required design considerations include:</p> <p>a) Required volume of oxygen to pressurise and ventilate the chamber, where oxygen-filled chambers are to be used.</p> <p>b) Facility supply should be large enough to support complete treatment. <i>Note: One litre of liquid oxygen evaporates to ±860 litres of gas at standard temperature and pressure (1 cf of liquid produces 860 cf of gas).</i></p> <p>c) Supply piping should be sized to support chamber maximum flow demand without affecting the health care facility's other requirements.</p> <p>d) Where liquid (cryogenic) oxygen is to be used, the supply company should do the appropriate storage tank sizing. As a guideline, a supply system would be based on pressurisation requirement (volume times depth in ATA) plus ventilation to provide complete treatment cycle for the maximum intended number of treatments (per tank refill period). A 50% boil-off ratio is usually assumed and at least a 30% safety margin included.</p>
1.4.10	Chamber oxygen supply and exhaust systems	An inadequate supply of therapeutic oxygen can compromise a treatment regimen and thus negatively affect the outcome for the patient.	3 3	<p>The design of a chamber's supply and exhaust systems should meet the following criteria:</p> <p>a) It should be capable of ensuring a supply pressure of at least 0.35 MPa (50 psi) above the chamber's pressure to each outlet, or as otherwise required by the selected breathing apparatus;</p> <p>b) It should be equipped with emergency isolation valves, preferably fitted close to the shell;</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Chamber oxygen supply and exhaust systems (cont.)	<p>In air-filled monoplace chambers, exhaling oxygen or leakage from the breathing mask into the chamber, can elevate the chamber oxygen level above 23.5%, thereby constituting a risk of fire.</p> <p>Failure of the overboard dump system may expose the patient or attendant to the risk of severe suction injuries.</p>	<p>3</p> <p>3</p> <p>3</p> <p>4</p> <p>4</p>	<p>c) It should include sufficient capacity to permit treatments to be completed prior to refilling;</p> <p>d) Provide for a secondary (reserve) supply of oxygen in the event that the main service is interrupted;</p> <p>e) It should ensure that HP supplies conform to the guidelines for a safe and controlled supply;</p> <p>f) Where restricted ventilation is used (less than 250 litres per minute [lpm] or 8.8 cfm), the patient breathing apparatus exhaust system is fitted with an effective overboard dump process, which automatically adjusts to the treatment pressure; and</p> <p>g) It should ensure that the exhaust system has been designed to restrict or control the flow between the patient and ambient pressure.</p>
1.4.11	Cryogenic supply system	<p>Inadequate maintenance, poor housekeeping, and/or lack of regular inspection of the cryogenic supply system presents a risk of fire, supply interruption, and/or facility damage.</p> <p>Even if the filling and maintenance of the system are handled by an outside vendor, the chamber facility's owners and managers still bear responsibility for ensuring the integrity, safety, and availability of the system.</p>	<p>3</p> <p>3</p> <p>3</p> <p>4</p> <p>3</p> <p>3</p>	<p>If the facility has a cryogenic supply system, it should conform to all applicable statutes and regulations, should be controlled and managed by a <i>competent</i> gas supply company, and should be properly maintained, at a minimum with respect to these factors:</p> <p>a) The security of the site, to prevent unauthorized access or interference with the system;</p> <p>b) Routine monitoring of fire hazards, such as removal of under- or overgrowth, overhead electrical supply lines, or burnable materials (including waste matter) stored in the immediate vicinity of the system;</p> <p>c) The placement and integrity of adequate warning signs and emergency instructions;</p> <p>d) Regular inspections (at least prior to each treatment session) of the cryogenic storage area, including monitoring of liquid/gas storage levels, system pressures, control positions, equipment condition, and site security; and</p> <p>e) Appropriate and regular maintenance by an appointed, <i>competent</i> gas supply company.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.14	Air chamber ventilation requirements	<p>Inadequate ventilation can have an impact on patients' condition, allow a buildup of oxygen and/or carbon dioxide (CO₂), and affect the temperature and humidity in the chamber.</p> <p>Such conditions increase the risk of fire and/or toxic gas levels, as well as of other risks associated with elevated temperature and humidity.</p> <p>Such risks exist during all stages of chamber operation, including pressurization, a constant-pressure state, and depressurization.</p> <p>Poorly placed inlet and exhaust points may also result in inadequate circulation and ineffective removal of unwanted gases.</p>	<p>4</p> <p>3</p> <p>3</p>	<p>a) A minimum* ventilation rate of 64 <i>actual</i> lpm (2.3 acfm) per chamber patient is required. (<i>Actual</i> flow implies the rated flow at the chamber's ambient pressure and temperature.)</p> <p>This rate may be reduced when the patient is breathing oxygen using an overboard dump system, providing that oxygen levels remain below 23.5%.</p> <p>The minimum ventilation rate should always be implemented when a mask is not being used by the patient(s) - such as during an air-break.</p> <p><i>*The ventilation rate may need to be increased where no overboard dump system is fitted, or where the overboard dump system is not effective, in order to be able to keep oxygen levels below 23.5%.</i></p> <p><i>The guidelines for oxygen chambers specified in section 1.4.15 below should be adhered to.</i></p> <p>b) Inlet & exhaust points should be located so as to ensure effective circulation, scrubbing out of unwanted gases, lowering of the chamber internal temperature and reduction of humidity levels.</p> <p>c) Stable conditions may be maintained by scrubbing to remove CO₂ and odour levels.</p>
1.4.15	Oxygen chamber ventilation requirements	<p>Ventilation rates can have a detrimental effect on patients. Patients with large burns could suffer unacceptable evaporative heat loss making them hypothermic.</p>	<p>4</p> <p>3</p> <p>3</p>	<p>During the initial pressurization period, the chamber needs a high ventilation rate to remove all nitrogen from the initial air charge. A ventilation rate of at least 240 lpm, (8.5 scfm) will ensure that the ambient oxygen levels rise rapidly.</p> <p>Based on the size of the chamber, this rate may be reduced to the minimum level of 85 actual lpm (acfm) for the remaining duration of the treatment.</p> <p>Recycling gas systems also allow for lower ventilation rates.</p> <p>As it is often impractical or unsafe to change ventilation control systems, medical staff should be aware of specific patient requirements and provide appropriate, alternative or compensatory measures.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.16	Conditioning of chamber environment	Inadequate ventilation and uncomfortable temperatures compromise patient condition. Uncomfortable conditions heighten patient anxiety levels, can cause medical problems and affect the control of static electricity.	2	Chambers should ideally be maintained at a temperature of $22^{\circ} \pm 2^{\circ}\text{C}$ ($72^{\circ} \pm 5^{\circ}\text{F}$) and a relative humidity of 40% to 60%. This can be achieved through the use of ventilation using suitably conditioned gas.
1.4.17	Emergency or back-up supply	Interruption of oxygen supply could compromise treatment as well as patient condition.	4	A secondary (reserve) supply of oxygen should be provided in the event that the main service is interrupted. Use of limited quantities of HP oxygen, suitably regulated, is usually deemed sufficient.
Chamber piping considerations				
1.4.18	Gas supply pipe sizing	Incorrectly sized pipelines could compromise treatments, patient condition as well as the health care facility's other requirements.	3	<ul style="list-style-type: none"> a) Pipelines to the HBO treatment facility should be sized according to the maximum demand requirement - typically 20 mm ($\frac{3}{4}$") for a required flow per chamber of 700 lpm (25 scfm). 3 b) Pipe length has a direct bearing on size, as pressure loss is directly proportional to length. 3 c) Longer lengths may require compensation for pressure losses by increasing diameter. 3 d) The system manufacturer usually specifies pressure available at the chamber. 3 e) As a guideline, chambers require a minimum of 0.35 MPa (50 psi), or typically 0.55 MPa (80 psi) where a ventilator is fitted (or as required by the ventilator manufacturer). 3 f) Maximum pressure is usually limited to 0.55 MPa (80 psi). 3 g) Oxygen supply lines should have a safety shut-off valve immediately adjacent to the treatment area and readily accessible to the facility personnel.
1.4.19	Oxygen supply control panel	Control of oxygen supply is essential for safe and effective treatments, as well as during emergencies.	3	A separate oxygen supply point and shut-off valve should be provided for each chamber.

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.20	Chamber supply pressure	Visual indication of regulated gas supply to the chamber is necessary to ensure safe commencement of treatment, as well as during treatment.	4	A downstream indicating pressure gauge, preferably mounted on the chamber control panel, should be fitted to allow visual monitoring at all times by the operator. Gauges should be checked at least once a year to ensure appropriate function (gauge should read zero where there is no supply pressure, and indicate the same supply pressure showing at the nearest supply point gauge, within at the most a 10% deviation).
1.4.21	Filtration	Dirt and construction debris may cause regulator failure, valve seat failure, calibration difficulties, poor or erratic chamber control, and even failure of critical control equipment.	3	An in-line filter should be installed immediately prior to the chamber control system. A 10 µm filter, with a flow capacity of at least 850 l/min (30 scfm) and rated at 1.5 times the maximum line pressure, should be used.
1.4.22	Oxygen toxicity	Oxygen toxicity is a known contra-indication of this form of treatment. Planned air breaks reduce the susceptibility to oxygen toxicity.	3	All chambers should preferably be fitted with a breathing air supply system to allow patients to be switched to air at the onset of toxicity symptoms, as well as for the application of regular air breaks.
1.4.23	Accidental mixing of gases	Accidental mixing of oxygen and air will compromise the treatment efficacy, as well as compromise patients being treated for toxicity symptoms.	4	Gas supply systems should avoid common gas manifolds, where gas mixing can occur and should at least include dual check valves to prevent back-flow into each gas supply line. Proven-safe and rapid switchover systems are achieved by introducing air through a separate supply piping system direct to the patient using a face mask. Oxygen is supplied through the system pressurisation and ventilation system. Alternatives include valve interlocks or block-and-bleed piping arrangements to ensure that only one gas can be supplied to the chamber at any one time.
1.4.24	Piping systems	Certain materials are not suitable for hyperbaric facilities due to impurities and corrosion considerations.	4 3	a) Only* copper, brass alloys, or stainless-steel alloys should be considered for supplies to the chamber. b) Materials for exhaust systems are required to be oxygen-compatible but are not otherwise restricted.

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Ref.	Element	Risks	RL	Minimum Requirements
	Piping systems (cont.)	<p>Undersized piping systems affect patients by prolonging treatments unnecessarily, restricting extraction of patients during emergencies, and generating excessive noise.</p> <p>Venting systems can cause injuries to patients if inlets are not suitably screened.</p> <p>Malfunctioning, leaking, damaged or seized valves allowing gas to flow either into or from the chamber may lead to uncontrollable pressurization or depressurization. This could occur either insider or outside the chamber.</p> <p>The use of HP supplies can result in the overpressurization of piping and/or other components beyond their rated levels.</p> <p>Inadvertent over-pressurization can also occur if the control equipment fails, or if the operators fail to control pressures correctly.</p> <p>Dirt particles are a known source of failure of regulators to maintain constant downstream pressure.</p>	<p>3</p> <p>4</p> <p>4</p> <p>2</p> <p>3</p> <p>3</p> <p>4</p>	<p>c) Supply piping systems should be designed provide the maximum flow required under all conditions. Refer to the requirements specified in section 1.4.18 above.</p> <p>d) Exhaust systems should be capable of surfacing (decompressing) the chamber from 3 ATA (29 psi) to ambient pressure in less than 2 minutes.</p> <p>e) All exhaust inlets, relief valves, depth monitoring inlets, sample inlets, and other suction inlets inside the chamber should be fitted with anti-suction-injury devices.</p> <p>f) All shell penetrations should be fitted with external isolating valves, as close to the penetration as possible, to allow the gas flow to be shut off in the event of a malfunction. <i>It is accepted that many modern monoplace chambers do not have shell valves. The Safety Officer will need to make an appropriate risk-mitigating decision in this regard.</i></p> <p>g) Chambers should only be pressurized using regulated, low pressure (LP) gas, in accordance with manufacturer's specifications. <u>Note:</u> HP gas supplies, i.e., those > 4 MPa (>580 psi), should be reduced as close to the source as is practical.</p> <p>h) All pressure reducing regulators should be fitted with downstream pressure-relief devices in order to protect piping and/or components that are rated for lower pressures.</p> <p>i) The inlets to all pressure-reducing regulators should be fitted with suitably sized particle filters ($\leq 10 \mu\text{m}$) to prevent dirt or debris from entering the sensing ports and causing downstream regulator creep.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
	Piping systems (cont.)	<p>Systems designs that rely on operator attentiveness to prevent certain actions - including back-filling of storage vessels at different content levels, reverse pressure or - flow situations (especially on systems with diaphragms and/or sensing equipment) and venting through unintended flow-paths, can compromise supplies, lead to inaccurate assessments of available gases, and/or result in the failure of pressure-control equipment.</p> <p>Inappropriate or inadequate cleaning procedures may result in premature component failure or the introduction of toxic vapours into the chamber, and can increase the risk of fire.</p> <p>Failures of computer or remote pneumatic control systems are complex and can easily result in loss of control.</p>	<p>3</p> <p>3</p> <p>4</p>	<p>j) The piping of supply systems should be fitted with nonreturn (check) valves to prevent the following actions:</p> <ul style="list-style-type: none"> • inadvertent back-filling of storage vessels; • exposure of regulators and/or other components to reverse-pressure situations if they were not designed for such applications; and • venting through self-venting ports on pressure-reducing regulators. <p>k) All system components and piping should be suitably cleaned prior to first use.</p> <p>l) All computerised or remote-control systems should be designed with adequate back-up facilities as well as manual overrides. Ref. also section 1.4.31.</p>
1.4.25	Oxygen piping	<p>Compressed oxygen represents a risk of fire and other effects of its stored energy.</p> <p>Inappropriate or inadequate cleaning procedures can result in premature component failure, or the introduction of toxic vapours into the chamber and can increase the risk of fire.</p> <p>Certain piping materials are not suitable for use with oxygen.</p>	<p>4</p> <p>4</p> <p>4</p> <p>4</p>	<p>Oxygen piping should be designed and installed according to the following minimum requirements:</p> <p>a) Only <i>competent</i> and thoroughly trained individuals should install, clean or work on oxygen piping systems.</p> <p>b) If copper tubing is brazed, it should be continuously purged using nitrogen to prevent the formation of hazardous copper oxides.</p> <p>c) All oxygen supply lines should be cleaned in accordance with an approved oxygen cleaning procedure.</p> <p>d) Only oxygen-compatible materials may be used (publications of the ASTM [American Society for Testing and Materials], CGA [Compressed Gas Association] and ASME/PVHO contain lists of approved materials).</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Oxygen piping (cont.)	<p>In the event of a fire, the oxygen supply to the chamber room would likely exacerbate the fire.</p> <p>Rapid acting valves are a potential source of adiabatic heating during opening and closing.</p> <p>The use of HP supplies can result in the overpressurization of piping and other components, not intended for elevated pressures.</p> <p>High pressures can also be introduced inadvertently if control equipment fails or if an operator fails to control pressures correctly.</p> <p>Dirt particles are a known source of the failure of regulators to maintain constant downstream pressure.</p> <p>System designs that rely on operator attentiveness to prevent certain actions – including back-filling of storage vessels at different content levels, reverse-pressure or -flow situations (especially on systems with diaphragms and/or sensing equipment), and venting through unintended flow paths – can compromise supplies, lead to an inaccurate assessment of available gases, and/or result in the failure of pressure-control equipment.</p>	<p>4</p> <p>4</p> <p>3</p> <p>3</p> <p>4</p> <p>3</p>	<p>e) An oxygen shut-off valve should be installed at the point where the oxygen enters the room.</p> <p>f) Quick-acting ball valves may be used to isolate incidents of LP (i.e., < 0.86 MPa [125 psi]). However, quick-acting ball valves should not be used for the isolation of lines containing oxygen at pressures above 0.86 MPa (125 psi).</p> <p>g) HP oxygen supplies, i.e., those > 4 MPa (580 psi), should be reduced at their source, or, if that is impractical, at the chamber control station.</p> <p>h) All pressure reducing regulators should be fitted with downstream pressure-relief devices in order to protect piping and components rated for lower pressures.</p> <p>i) The inlets to all pressure reducing regulators should be fitted with suitably sized particle filters ($\leq 10 \mu\text{m}$) to prevent dirt from entering the sensing ports and causing downstream regulator creep.</p> <p>j) Oxygen supply systems should be fitted with non-return (check) valves to prevent: inadvertent back-filling of storage vessels; exposing regulators and other components to reverse pressure situations, where these are not intended for such applications; and to prevent venting through self-venting ports on pressure reducing regulators.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Oxygen piping (cont.)	Piping joints, both welded and re-useable connections, are known areas where oxygen under pressure can leak out.	3 3	<p>k) After installation and at prescribed maintenance intervals, oxygen piping should be tested for leaks. Due caution should be exercised when using non-oxygen compatible or flammable test solutions.</p> <p>l) Only special, dedicated tools should be used for oxygen service (i.e., cleaned and non-sparking).</p>
1.4.26	Oxygen exhaust system	<p>Uncontrolled exhaust of oxygen constitutes a physiological and fire risk.</p> <p>Back-pressure may be caused by inappropriate design and slow the duration of ascent; this is specifically hazardous in the event of an emergency situation requiring rapid depressurization.</p>	4 3 3 3 4 3 4	<p>The design of the exhaust equipment, including the discharge from any safety-relief device(s) into an enclosed space or into the chamber room, should be connected to an exhaust line piped into a safe open space.</p> <p>In addition, the exhaust system should:</p> <p>a) Be fitted with emergency isolation valves, preferably fitted close to the chamber shell;</p> <p>b) Contain a line length of no longer than 5 m (16 ft) unless sized to eliminate gas flow back-pressure;</p> <p>c) Preferably be separate from any other exhaust lines;</p> <p>d) Contain no flow obstructions at or near the outlet; and</p> <p>e) A screen at the outlet should be considered to prevent birds and insects from entering and causing obstructions, such as nests. In addition, where exposed to rain, the outlet should face down.</p> <p>f) Not terminate near a source of heat, an ignition sources, or a hazardous area.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.4.27	Flexible hoses	<p>Due to more frequent connection & disconnection, and/or an intrinsically weaker structure, flexible hoses are more prone to failure due to mechanical damage, surface abrasion, material age- or environmental related degradation and cracking, and weakening of end fittings.</p> <p>Any of these can result in a rapid and even catastrophic failure, with the associated expansion-related damage, or unrestrained hoses whipping around and cause significant damage.</p>	3	<p>In selected cases, the use of flexible hoses for gas supply systems is acceptable, subject to the following criteria:</p> <ul style="list-style-type: none"> • Be kept to a minimum, except for LP exhaust lines; • Preferably be restricted to short lengths (<1 m [3 ft]) where used for HP (> 4 MPa [580 psi]) gas applications; • Where longer lengths need to be used, these should be fitted with restraints (anti-whip devices); • Be suitably rated and appropriately certified for the system design pressure; • Be consistent with cleanliness requirements and compatible with the gas they will transport; • Be connected without any stress on joints and couplings; • Be assembled without kinks or sharp bends; • Be adequately protected from external, mechanical damage; • Not pose a trip hazard; • Be used only where adequate provision has been made for the regular inspection of the condition of all flexible hoses. • Shut-off valves should be located as close to the chamber as is practical. • Consideration may be given to the use of a check valve in a flexible hose connected directly to a chamber, as a buffer in the event of a line break.

Breathing Apparatus

1.4.28	Internal breathing apparatus	<p>Ineffective supply of therapeutic gas compromises the quality of treatment and will affect the outcome of the patient.</p>	<p>4</p> <p>5</p> <p>4</p>	<p>Where this is fitted, the breathing apparatus and supply system should be designed such that:</p> <ul style="list-style-type: none"> a) it is independent of chamber atmosphere b) it is fully functional at all chamber operating pressures; c) where a demand system is used, it is capable of sustaining the supply pressure above chamber pressure required by the installed breathing apparatus;
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1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Internal breathing apparatus (cont.)		4 4	d) where a mask exhaust system is used, it is fitted with an effective overboard dump system, which automatically adjusts to treatment pressure and includes some type of vacuum relief; and e) in the event of fire, the supply can be switched to air (or a suitable, normoxic mixture).
1.4.29	External self-contained breathing apparatus	In the event that the air in the vicinity of the chamber is fouled by smoke or combustion products, the chamber operator may (due to the complexity of a given chamber treatment), be unable to immediately depressurise the chamber and evacuate the patient to safety. In such a case, the operator faces the risk of breathing the fouled air unless an external self-contained breathing apparatus is available.	4 4	a) An independent source of breathing air or a suitable filtered breathing set should be available for use by essential chamber personnel in the event that the air in the vicinity of the chamber is rendered toxic, fouled or generally unbreathable. b) Suitable eye protection to shield chamber personnel from combustion products should be incorporated into the breathing apparatus.
General Gas System Requirements				
1.4.30	Sound attenuation	The chamber environment presents numerous acoustic problems that serve to magnify noise levels.	3 3 2	a) Mufflers should be used to reduce noise to the levels required by national regulations, or at least below 85 dB(A). b) Noise levels during maximum flow situations, including emergency ascents, should be considered and verified. c) Reverberation should be reduced through the use of baffling panels.
1.4.31	Power-operated or automatic chamber control system	Automatic control systems may provide better control and allow the operator to focus on the patient rather than the controls. However, in the event of any system failures, the chamber and the patient may be placed at risk from rapid ascent or descent, or the patient being locked in the chamber.	4	Internal valves are not considered appropriate for clinical monoplace chamber applications. The operator must therefore have the means to override or deactivate the control system to manually control the chamber. This should include descent, ascent, ventilation rates, maintaining the chamber at constant treatment pressure and deactivating the door interlock when the chamber reaches the surface.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.5 Fire Protection

1.5.1	Fire protection for Class B chambers.	<p>As of the date of this edition, NFPA has no fire protection (extinguishment) requirements for Class B chambers.</p> <p><i>Note: When considering the combination of accelerated burn rate in oxygen filled chambers and the inability to extinguish a fire until the majority of oxygen is depleted or removed, there is currently no feasible fire suppression technology for oxygen-filled chambers that would simultaneously be effective and insure survivability of the patient.</i></p>	5	<p>Fire risks need to be dealt with by operators on the outside.</p> <p>Gas quality, patient preparation, facility management and equipment design parameters are intended to prevent or mitigate fire and explosion risks.</p>
1.5.2	Fire alarm signal	<p>The chamber operator should not be expected to have to contact the fire and/or emergency services manually if an emergency situation occurs either within the chamber or in its immediate vicinity.</p>	5	<p>A fire alarm and/or emergency signalling device should be provided at the operator's console so that the nearest fire department can be contacted directly.</p> <p>A direct alarm/monitoring system coupled to the fire department is preferable.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.6 Electrical Systems

	<p><i>Note: Electrical equipment for use inside Class B chambers, whether pressurised on air or oxygen, is usually restricted to communications systems and patient physiological leads only.</i></p> <p><i>However, this requirement may be reconsidered where specific needs arise.</i></p> <p><i>Any such decisions require an in depth understanding of both electrical equipment and the risks associated with a potentially elevated oxygen environment.</i></p> <p><i>Warning: Electrical equipment that must be installed or brought into a hyperbaric chamber should be limited to a maximum voltage rating of 28 V_{DC}.</i></p> <p><i>Precautions should still be adhered to, as even low voltage switching can induce sparking with enough energy to ignite materials under normal conditions. These precautions should be adhered to even if the chamber door is still open or the chamber is not pressurised.</i></p> <p><i>High oxygen concentrations will remain present inside the chamber long after completion of any treatment.</i></p> <p><i>It is prudent to also consider these precautions and requirements as applicable for all electrical equipment physically installed onto the chamber (including control consoles, door interlocks, patient monitoring panels and any other electrical device bearing structures).</i></p> <p><i>Comment: Although it is expressly stated that electrical equipment for use inside the chamber is to be limited to communications systems and patient physiological leads only, this Guide does provide additional guidelines and requirements for consideration where exceptions to this rule are considered (based on specialist and professional input, and expressed permission and acceptance by the Safety Officer) as well as for installation of electrical equipment onto the chamber.</i></p>			
1.6.1	Electrical regulations	Electrical wiring and equipment outside the chamber but within HBO facilities may present several unique hazardous conditions. Local electrical regulations impact on safety aspects external to the chamber, as these are designed to meet local operating and supply conditions.	4	NFPA 70, National Electrical Code® contains applicable regulations that have been considered by the NFPA-99 committee. Either this Code or, as a minimum, local electrical regulations as applicable to AC distribution and wiring, should be adhered to.
1.6.2	Location of service equipment, switchboards, distribution boards & control panels	Switching of all forms of electrical power can produce sparks that contain more than sufficient energy to ignite a flammable agent.	3	All electrical service and high voltage (i.e., above 28 V _{DC}) should be located away from the hyperbaric chamber.
1.6.3	Energised electrical equipment built into oxygen-piped consoles	The combination of leaking oxygen piping and energised electrical equipment creates a risk of fire.	4	If control consoles contain both oxygen piping and electrical equipment, the console should be constantly ventilated, or the electrical equipment should be isolated from any oxygen leak by being separately enclosed. If neither is done, the console space should be monitored for excessive oxygen concentrations.

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.4	Location of switches, switch panels, circuit-breakers, line-fuses, relays, ballasts, motor controllers, transformers & power supplies	Switching of all forms of electrical power, even on low power lines, can produce sparks. Energy storage devices can produce sparks when switched or rapidly discharged. Sparks are a proven source of ignition.	5	No exposed switching devices and no power sources should be installed within a hyperbaric chamber. If switches need to be installed, refer to section 1.6.12 for guidance. Power supplies for internal equipment should be installed outside the chamber, according to the following criteria: a) For alternating current (AC) power, an ungrounded isolated power supply (IPS) should be used. b) For direct current (DC), an appropriately shielded transformer providing ungrounded power and including suitable protection (a fuse, trip switch or circuit breaker) to protect against any current overload should be used.
1.6.5	Protection from water deluge	Electrical equipment that is exposed to immersion or flooding by external sprinkler & deluge systems may fail. Patient outcomes and safety procedures can thereby be affected.	5	All critical equipment should be protected from the effects of water-based fire-suppression systems. If that is not possible, any safety-critical equipment should be able to function long enough to allow the patients to be decompressed if necessary.
1.6.6	Reserve power supplies	If critical equipment fails due to a building or municipal power failure, the chamber patients can be compromised where lighting and communications systems fail. The chamber environment may become hazardous while monitors are down, patient monitoring equipment may fail, safety equipment may be rendered inoperable, and the	4	a) All critical equipment - including chamber lighting and emergency lighting, communications (and including emergency communications, if applicable), alarm systems, fire detectors, fire-suppression systems, chamber pressure controls and monitors, patient monitors, infusion pumps and ventilators, and environmental monitors - should be connected to either the health care facility's emergency electrical system, or, preferably, an independent back-up system.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	<p><i>Note: Ref. 1.6.9 through 1.6.17</i></p> <p><i>Electrical equipment for used inside oxygen chambers should be restricted to communications and patient physiological leads only, unless specific safety measures are followed, as detailed in the sections below.</i></p>			
1.6.9	Chamber wiring & equipment	<p>Class B Chambers rely on a higher degree of safety due to the inability to deal with electrical hazards and the likelihood of elevated oxygen levels.</p> <p>Inappropriate electrical wiring and unsuitable electrical equipment can present a risk of explosion, electrocution or implosion in a chamber environment.</p> <p>Contact with “live” parts can affect the human body in the following ways:</p> <ol style="list-style-type: none"> 1) Tetanization, or the involuntary contraction of affected muscles, which can make it difficult to let go of a live component. † 2) Breathing arrest, due to involuntary contraction of the muscles that control the lungs, which can alter the normal respiratory process. † 3) Ventricular fibrillation, or the superposition of an external current with physiological currents leads to uncontrolled contractions and this induces alterations of the cardiac cycle. † 4) Burns, due to heating caused by current passing through the body. ‡ <p>† AC power ‡ AC or DC power (Joule effect)</p> <p>Most standard electrical equipment is not designed to operate in or near pure oxygen environments.</p>	<p style="text-align: center;">3</p> <p style="text-align: center;">3</p>	<p>a) For any wiring or equipment used in Class B Chambers:</p> <ul style="list-style-type: none"> • Circuits shall not exceed 28 V_{DC} and 4.0 W. • Permanent wiring shall be protected from physical damage. • Patient physiological leads shall be part of equipment compliant with this section. <p>b) A range of medical monitoring devices and support equipment is available to improve the quality of care to patients.</p> <p>To accommodate the use of some of this equipment, the following requirements and guidelines should provide a sound, safe basis for the application of user discretion and engineering judgement, (irrespective of whether the chamber door is closed or not):</p> <ul style="list-style-type: none"> • The requirements for Class 1, Division 2 locations should be followed as a general rule for any electrical wiring and equipment located in a chamber. However, it is not a requirement that chambers be classified as Class 1 locations. • NFPA 70 Article 500 provides guidance on selection of equipment and design of wiring for this class of environment. • Only the minimum amount of electrical equipment deemed necessary for patient care should be permitted inside the chamber. • All equipment and wiring intended for use within a chamber should be tested and approved for such use, especially in the case of oxygen chambers. • Standard medical industry equipment should not be altered for use inside a chamber unless such alterations are sanctioned by the original manufacturer, or by a competent authority

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Chamber wiring & equipment (cont.)		4	c) In air-filled chambers, the oxygen level should be continually monitored, and the alarm should sound when it rises above 23.5%.
			4	d) Advice from a competent electrical design authority should be sought to ensure compliance and safety.
1.6.10	Insulation of conductors	Uninsulated conductors represent a source of sparks. The composition of the insulating material may also present an environmental hazard if it's exposed to heat or fire.	3	All conductors used inside a chamber should be insulated using a flame-resistant material. Ground conductors encapsulated within equipment do not necessarily require insulation.
1.6.11	Receptacles & plugs	Interruption of any powered circuit can produce sparks sufficient to ignite a flammable agent. Unsecure and unground connections are a possible source of shock and arcing. Drenching from the room deluge system can cause short circuits in unprotected, external connectors.	4 3 3 3 3	All plugs and receptacles should meet the following criteria: a) They should be of an approved type; b) They should be grounded; c) If used to power any equipment, they should be fitted with an interlocking mechanism to prevent withdrawal or insertion while they are energized; d) They should be fitted with a locking mechanism or be supplied with a label warning against unplugging them while they are under load; and e) They should be secured and protected against accidental damage by the patient.
1.6.12	Internal switches	Switches are a potential source of sparking.	4 4	It is recommended that all switching be done outside the chamber. If internal switching is necessary, it should be achieved using intrinsically-safe circuitry that drives external power and control circuits. If internal switches are used, they should meet one of the following criteria: a) They should be gas-tight; or b) If switches need to be installed, intrinsically-safe housings (i.e., rated for explosive environments) are required unless the switching capacity is < 25mW (e.g., piezo switches).

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.6.13	Monitoring of equipment temperature rating	Hot surfaces can be a source of ignition, especially within such potentially hazardous locations. The restricted space inside a monoplace chamber implies that the patient is less able to move away from any hot surface.	4	No equipment installed or allowed in a hyperbaric chamber should have any exposed surfaces where the temperature exceeds 50°C (122°F). <i>Note: This temperature threshold is based on the ignition-temperatures of materials commonly found inside HBO chambers, on the potential for fault conditions in oxygen and on the potential for thermal injury to the patient.</i>
1.6.14	Exposed live electrical parts	Exposed live (energised) electrical parts can be a source of shocks and/or sparks in the event of an electrical fault.	4	No exposed electrical parts (excluding patient monitoring leads) should be present in a HBO chamber unless they have been certified as being intrinsically safe.
1.6.15	Use of low-voltage, low-power equipment	Low voltage and low-power equipment are capable of producing sparks. Of even greater concern is the fact that it is capable of overheating under fault conditions.	4 3 4 3 3 3	All sensors and signalling, alarm, communications and remote-control equipment used or intended for use within a HBO chamber should meet the following requirements: a) Equipment should be isolated from AC power (also known as mains power) by either the power supply circuit design, opto-isolation, or by other electronic isolation methods; b) All leads and cables not enclosed within conduits should be either part of intrinsically safe equipment, or limited to less than 28 V _{dc} , 0.5 A and 4.0 W under normal or fault conditions; and c) The design of chamber speakers should be such that electrical circuitry and wiring are enclosed, and rating should not exceed 28 V _{rms} , 0.5 A and 4.0 W. Alternatively, the following equipment configurations are considered acceptable: a) Equipment listed as intrinsically safe for Class 1, Division 1, Group B locations; b) Equipment that is totally enclosed and constantly purged by means of an independently supplied, oxygen-clean air or inert gas source that automatically de-energises when the gas supply fails; c) Equipment that is hermetically sealed, filled with inert gas, positively pressurised, and fitted with an automatic de-energization device that activates if the initial pressure (i.e., when sealed) changes by more than 10%; or

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Use of low-voltage, low-power equipment (cont.)		3	d) Equipment that has been approved for use by a <i>competent</i> authority and that has the written permission of the Safety Officer.
1.6.16	Patient-care devices	The risks associated with the use of electrical medical equipment in a chamber include current leakage, unvented batteries, off-gassing of batteries, sparking, heat-generation, and/or explosion or implosion due to inadequate venting.	<p style="text-align: center;">3</p> <p style="text-align: center;">3</p> <p style="text-align: center;">3</p> <p style="text-align: center;">4</p> <p style="text-align: center;">4</p> <p style="text-align: center;">4</p>	<p>In addition to the limitations noted above (i.e., a surface temperature of less than 50°C [122°F], an operating voltage of 28 V_{DC} or less, and adequate certification and/or testing for use within monoplace chamber environments), any patient-care devices used within a chamber should meet the following minimum requirements:</p> <p>a) They should be designed and verified as safe for patient-care applications (e.g., per NFPA 99);</p> <p>b) Their electrical and mechanical integrity should be continuously monitored under the facility’s maintenance program;</p> <p>c) Any devices that utilize oxygen should be designed so that oxygen cannot accumulate in electrical sections under any conditions;</p> <p>d) Charging of batteries inside a Class B chamber is expressly forbidden and</p> <p>e) The devices have been successfully tested for proper performance over the chamber’s full operating pressure range.</p>
1.6.17	Use of portable battery-operated electrical or electronic equipment	Any sources or users of electrical power can generate sparks and/or heat. In addition, batteries are a source of toxic and/or flammable gases under fault or heavy load conditions.	<p style="text-align: center;">4</p> <p style="text-align: center;">5</p> <p style="text-align: center;">5</p>	<p>Implantable devices and certain essential, medical support equipment, using low power, disposable batteries, may be required for essential patient support.</p> <p>All such equipment – including permanently installed sensors; communications devices; and signaling, alarm, or remote-control equipment – should meet the following criteria:</p> <p>a) Batteries should be fully enclosed and secured within the equipment enclosure;</p> <p>b) Batteries should be compatible with the chamber’s maximum operating pressure and be of a sealed type that does not off-gas during normal use;</p> <p>c) Batteries should not be charged while they are inside the chamber;</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Use of portable battery-operated electrical or electronic equipment (cont.)		4 4 4	<p>d) Batteries should not be changed while the equipment is located inside the chamber;</p> <p>e) Lithium-ion batteries should be excluded completely unless they are monitored during use for any temperature increase that could result in overheating; and</p> <p>f) The equipment's electrical rating should not exceed 28 V_{DC}, 0.5 A and 4 W.</p>
1.6.18	Chamber grounding	<p>Inadequate grounding compromises the effective functioning of a chamber's IPS as well as any intrinsically safe equipment.</p> <p>Static build-up and isolated (ungrounded) metallic structures represent ignition potential when discharged in oxygen-enriched environments.</p>	4	<p>The resistance between the chamber and the ground point should not exceed 1 ohm.</p> <p>Chambers should be connected to earth ground by independent, 6 AWG (copper) cables.</p> <p>All chamber electric equipment, as well as bunks/stretchers, should be grounded to the chamber.</p>
1.6.19	Protected equipment outside of chamber	A failure of critical electrical equipment in the event of flooding by a sprinkler system compromises the safety of the patient.	4 3 4 3	<p>a) All equipment that must remain functional for the safe completion of a treatment after activation of a sprinkler system should be adequately waterproofed.</p> <p>b) Any conduits should be waterproof and, as applicable, be equipped with drains.</p> <p>c) All electrical circuits should be protected so that flooding by water does not constitute a further hazard.</p> <p>d) All electrical equipment should meet national regulations.</p>
1.6.20	Ground Fault Interrupter (GFI)	Electrical faults are a known source of ignition, equipment failure and even shock.	3	<p>a) All users of electrical power external to the chamber, including patient-support equipment, should be supplied from a GFI, line isolation transformer system – providing an inductive link only, as well as indicator/warning lights.</p> <p>(Earth-leakage protection, achieved using a residual current device [RCD], a practice used in some countries, may fulfill these requirements.)</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
	Ground Fault Interrupter (GFI) (cont.)		3	<p>b) The sensor should be set to activate at a fault current of 30 mA within 300 ms or more stringent, as determined by the electrical system design engineer.</p> <p><i>Note: If power is provided via a double-isolated transformer and if a dedicated grounding system is in place, the fault current may be increased to 20 mA (Underwriters Laboratory [UL] 943 Class C).</i></p>
			3	<p>c) The full load rating of the GFI should be twice the current rating of the equipment being used.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.7 Communications & Monitoring

	<p><i>Warning: Ordinary communication equipment is not suitable for use within hyperbaric chambers due to the potential for sparking from switches and arcing from microphones. This presents a distinct fire hazard. However, communication equipment is mandatory for the safe operation of the chamber, requiring special provisions to be adhered to.</i></p> <p><i>Remark: "Electrical" requirements have been detailed under the previous section, 1.6, and are not repeated here. However, compliance with the electrical equipment requirements remains mandatory in order to assure the required level of safety.</i></p>			
1.7.1	External communications equipment Internal communications equipment	Control equipment, including power amplifiers, output transformers and monitors are generally capable of producing a source of electrical discharge. The hazards associated with internally installed transducers and communications equipment have been detailed under <i>Low-voltage, low-power equipment</i> .	5	All such control equipment should only be installed for use outside of the hyperbaric chamber. The requirements as detailed under <i>Low-voltage, low-power equipment</i> in section 1.6.15 should be complied with.
1.7.2	Inter-communication	Any hazards associated with chamber operation, fire, patient safety and medical therapy cannot effectively be avoided and controlled where a breakdown in communications between the operator and patients occurs.	4	A continuous communication link between the operator and the hyperbaric chamber should be in place when the chamber is in use. Communications channels are to be kept open at all times.
1.7.3	System components	All electrical systems present hazards associated with electrical energy discharge and patient electrocution.	5	All AC systems should be located outside of the chamber. Chamber communicators should have a maximum voltage rating of 28 V _{DC} . The internal communicator should be designed for hyperbaric and high oxygen environment applications.
1.7.4	Entertainment systems	Television and radio circuits are potential sources of electrical energy discharge.	4	All entertainment systems should be fitted externally and set away from the chamber. TV and radio systems, where attached or connected to the chamber, including external chamber communication systems with voltage ratings exceeding 28 V _{DC} , should be supplied through the GFI.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.7.5	Patient monitors	<p>Patient monitors and equipment, and the associated hazards have been addressed previously under the electrical guidelines (section 1.6).</p> <p>An additional risk identified is the possibility of the patient pulling out leads.</p>	3	<p>Only low power, physiologically electrical signals (e.g., ECG, EEG) should be conveyed through the chamber. Internal and external electrical connectors should be used on all wiring harnesses.</p> <p>Other monitor leads should be protected through the design of through-hull penetrations.</p>
Chamber atmosphere monitoring				
1.7.6	Oxygen (O ₂) in air-filled Chambers	<p>Oxygen levels above 23.5% will increase flame propagation exponentially and are classified as highly dangerous.</p> <p>Oxygen levels below the safe partial pressure for a specific chamber pressure, especially applicable where diluent gases are introduced, may result in a hypoxic environment.</p> <p>Where an air-filled chamber has not been designed to contain oxygen enriched atmospheres, additional fire and failure risks may exist.</p>	5	<p>Oxygen levels in air chambers should be monitored at all times. Visual and audible alarms should indicate oxygen concentrations above 23.5% or below 19.5%.</p> <p>Air chambers not designed for oxygen enriched atmospheres should not be operated with interior oxygen levels above the safe limit of 23.5%.</p>
1.7.7	Carbon dioxide (CO ₂)	<p>CO₂ levels build-up during long treatments where little or no ventilation is used.</p> <p>High CO₂ levels are dangerous to all patients and potentiate oxygen toxicity.</p> <p>CO₂ intoxication may be insidious.</p>	3	<p>In air-filled chambers, if ventilation is not (or cannot be) used, CO₂ levels within the chamber should be monitored continuously.</p> <p>Visible and audible alarms should indicate CO₂ concentrations above the safe surface equivalent value (SEV) relative to treatment pressure (depth).</p> <p><i>The SEV represents the equivalent of the CO₂ level at pressure to the level at the surface:</i> $SEV = CO_2 \times \text{pressure in ATA}$</p> <p><i>For example, an allowable CO₂ exposure level of 0.5% (5000 ppm_v) implies a maximum allowable level (SEV) at 2.8 ATA (26 psi) of $5000 \div 2.8 = 1786 \text{ ppm}_v$, as measured by the analyser at the chamber control panel.</i></p>
1.7.8	Combustible gases	<p>Where flammable gases are used within a chamber, any leak or compromised gas-discharge circuit will create an immediate explosion hazard.</p>	5	<p>Flammable gases should not to be used.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.7.9	Chamber air supply monitoring	<p>Air may be provided either to pressurize the chamber (air-filled monoplace chambers) or for the air break in an oxygen-filled chamber.</p> <p>There are two possible sources of contamination of the chamber's air supply – contaminants in the ambient air and those added by the gas-compression equipment.</p> <p>If oil-lubricated compressors are used or if compressor intakes are positioned in areas that could be polluted by motor vehicle exhausts, toxins, oil vapour, or other HC contaminants can be rapidly introduced into the chamber's air supply.</p> <p>Toxic gases such as carbon monoxide (CO) can compromise the health of chamber patients. Oil vapours and other HC contaminants represent a known fire risk in an oxygen-enriched environment.</p> <p>Any air used in a piping system that is also used to convey oxygen requires additional attention due to the elevated fire risk.</p> <p>Oil-vapour coming into contact with oxygen is unavoidable due to the difficulty in effecting a secure and continuous seal on the patient mask.</p>	<p>4</p> <p>4</p> <p>3</p> <p>5</p>	<p>a) All compressors should be fitted with a suitable air-treatment package, capable of producing oxygen compatible air (OCA), i.e., medical air.</p> <p>b) The air should be sampled (preferably continuously but at least 6-monthly) for volatilized HC and CO downstream of the oil filter element as may be applicable.</p> <p>c) In addition, automatic safeguards, as specified in 1.4.5, should be installed.</p> <p>d) The required minimum specification for monoplace chamber air is detailed in Appendix B and summarised below.</p> <p>It is imperative to refer to this appendix prior to making decisions on air purity standards:</p> <p>Oxygen 20% to 22%</p> <p>CO₂ < 500 ppm_v</p> <p>CO < 5 ppm_v</p> <p>HC < 0.1 mg/m³ for liquid < 25 ppm_v (CH₄)</p> <p>Particles < 0.5 mg/m³ for particles > 5µm</p> <p>Odour Nil</p> <p>The allowable limit for H₂O vapour is based on actual supply (storage) pressure.</p>
<p><i>Recommendation: Oxygen chambers use limited quantities of compressed air for air-breaks. The use of certified medical air, supplied in HP form, complies with the stringent requirements for air purity in Class B chambers.</i></p> <p><i>Recommendation: Prior to deciding on a suitable air intake location, air should be sampled at the proposed compressor intake location at a time maximum impurities are expected to be present.</i></p> <p><i>At the discretion of the Safety Officer and where filter replacement schedules are strictly adhered to, hyper-filtration systems (which ensure CO < 2 ppm_v and oil content < 0.1 mg/m³) may replace the requirement for continuous monitoring. Periodic sampling of hyper filtered air is still a requirement.</i></p>				

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.7.10	Commercially supplied gases	It is possible to procure certified gases that have in fact not been analysed. Commercially supplied gases may contain contaminants in particulate form which present a fire risk in the piping systems and an explosion hazard in the chamber.	3 3 3 3	a) The Safety Officer should ensure that the commercial companies supplying certified gases have an adequate quality control system. b) Random sampling is strongly recommended to ensure quality of supply. c) Piping systems used to transfer gases from commercially supplied cylinders or containers should be fitted with particulate filters of at least 66 µm or finer. d) This does not replace the requirement to fit particulate filters (<10µm) at the inlet ports of the pressure regulators.
1.7.11	Visual monitoring of chamber interior	Inadequate surveillance of the chamber interior from the normal operating position can compromise the operator's response, and thus the patient's safety, if a dangerous or emergency situation develops.	5	Closed circuit TV monitoring should be employed wherever direct visual monitoring from the normal operating location is not possible.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.8 Other Equipment and Fixtures

	<p><i>Explanation: The selection and application of patient monitoring life-support equipment is complex and requires the combined attention of both the medical practitioner as well as the safety and engineering personnel.</i></p> <p><i>The UHMS Monoplace Hyperbaric Chamber Safety Guidelines, Chapter VI, contain significant details of both monitoring and life support equipment, including selection, installation, modification for monoplace hyperbaric applications, as well as operational considerations.</i></p> <p><i>However, in all cases, compliance with requirements as detailed in the rest of this document for electrical systems remains mandatory - ref. 1.6 above. Exceptions to the requirements should only be considered where clear expert and professional advice and endorsement is available.</i></p>			
1.8.1	Non-invasive monitoring:	Non-approved monitoring equipment may affect chamber and patient safety.	3	Sufficient approved brands of monitoring leads and lines are available which can be safely used within oxygen chambers.
1.8.2	Invasive monitoring	In general, invasive monitoring requires referencing at chamber ambient pressure. As monitors are located outside the chamber, the pressure gradient presents a direct risk to the patient.	4	Sufficient approved pressure compensatory techniques and equipment are available that allow safe invasive monitoring. However, this requires careful consideration by the medical director to ensure that mechanically-safe techniques do not present physiologically detrimental situations.
1.8.3	Intravenous infusion	The use of IV during a treatment contains a risk to the patient in the event of severing of the outside tubing.	4 3	a) All IV lines should be fitted with an approved check valve (one-way valve) fitted on the inside of the chamber. b) IV pumps should be the positive displacement type, capable of overcoming chamber internal operating pressure.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.8.4	Life-support equipment	<p>Many standard ventilators do not provide fixed or ambient pressure-independent tidal volume.</p> <p>External pacemakers are not approved for use inside oxygen chambers.</p> <p>Insufficient infusion pump output pressure may result in inadequate infusion feed rates.</p> <p>Uncontrolled suction lines may be hazardous or ineffective due to changing internal chamber pressure and the resulting variable suction force available.</p>	<p>3</p> <p>3</p> <p>4</p> <p>3</p> <p>3</p>	<p>a) Ventilators designed for use within chambers are available and should be used.</p> <p>b) External pacemaker leads should be passed through chamber bulkheads using approved penetrators.</p> <p>c) Infusion pumps are located outside the chamber and should be evaluated for ability to achieve supply pressures compensating for higher chamber pressures.</p> <p>d) Approved penetrators should be used to pass IV lines through the chamber bulkhead.</p> <p>e) Suction lines should be fitted with external fine-control valves, and preferably, automatic sensing pressure regulators should be fitted. Careful monitoring by medical staff should be performed where manual control is relied on.</p>
1.8.5	Patient resting devices	<p>Patients with cervical spine fractures may require in-line traction.</p>	<p>3</p>	<p>Special trays are required to provide continuous in-line traction to patients with spinal fractures.</p> <p>Such trays should comply with grounding, structural, material and oxygen compatible design considerations detailed elsewhere in this document.</p>
1.8.6	Permanently installed fixtures	<p>Ungrounded permanent fixtures isolate patients, thus enhancing the build-up of static electricity and reducing the effective functioning of the electrical protection and safety systems.</p>	<p>3</p>	<p>All permanently installed fixtures should be grounded.</p>
1.8.7	Exhaust systems	<p>Two hazards may be associated with exhaust systems, viz. noise and increased oxygen concentration at the outlet.</p>	<p>4</p> <p>3</p>	<p>a) Exhausts should be piped outside of the building, where the point of exit is clear of neighbouring hazards and possible re-entry of exhausts gases back into the building is unlikely.</p> <p>b) The exhaust exit points should be clearly identified and indicated with signage that prohibits smoking or any open flames in the immediate vicinity.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.1 Procedural Requirements

	<p><u>Explanation:</u> Suitable patient preparation, together with administration and records are fundamentally important aspects of the effective functioning of the hyperbaric facility and the safety and efficacy of hyperbaric treatments.</p> <p>The UHMS Monoplace Hyperbaric Chamber Safety Guidelines, specifically chapters VIII and IX, contain details of medical considerations required during assessment, orientation and treatment, together with administration and records.</p> <p>The majority of these sections are not included within the scope of the risk assessment process, as they are assumed to form part of the training, function and discretion of the responsible medical practitioner.</p>			
2.1.1	Standards	Minimum standards are required to ensure effective and safe treatment facilities.	3	<ul style="list-style-type: none"> a) Hyperbaric services that meet the needs of patients, as determined by the nature of the health care facility or practitioner, should either be available at all times, or within an acceptable notification period. 3 b) Facilities should be organised, integrated, staffed and directed commensurate with the scope of services offered. 3 c) The scope of services (medical and technical) should be clearly defined. d) This is essential to allow for proper transfer and referral of patients. 3 e) Patient support capabilities (e.g., IV infusion, ventilator support, vital signs monitoring) should be appropriate for the level of service provided.
2.1.2	Recognition of hazards	Until all risks associated with the hyperbaric facility have been quantified and mitigate, the facility may remain at risk.	5	<ul style="list-style-type: none"> a) The recognition of the multitude of hazards associated with hyperbaric facilities is a complex task. This document serves to identify the known risks and is intended as a guide to the appointed Safety Officer to identify and fully address all risks prior to commencement of operation. 5 b) Attention to detail by all administrative and maintenance personnel responsible for the functioning of the facility, will mitigate the hazards associated with the use thereof; and should be stipulated within the standard operating procedures of the facility.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.1.3	Personnel	The administration of hyperbaric oxygen therapy must be done by competent and thoroughly trained staff in order to ensure patients' safety, the efficacy of treatments, and the responsible practice of medicine.	4 4 4 4	<p>a) Staff appointments should be in writing; and should include clearly defined responsibilities. Staff should be delegated authority appropriate to their responsibilities. All units should employ the services of at least the following staff:</p> <p>b) <i>Medical Director</i> - a registered and suitably qualified, hyperbaric medical practitioner, responsible for all medical activities and for the direction, quality, safety and service provided by the facility. This person, or qualified designate, should be available throughout all treatments.</p> <p>c) <i>Safety Officer</i> - an appropriately qualified and <i>competent person</i> who is responsible for all equipment, operations and maintenance, and who is authorised to control the access of equipment and supplies to the. This person should be involved in all aspects of planning, regulations and use of the facility.</p> <p>d) <i>Technical Supervisor/Technician</i> - a trained and certified hyperbaric medical technologist (who may be a nurse, diving medical technician, or other suitably trained person), who is delegated, depending on the scope of services, the supervision of hyperbaric personnel, operation of the equipment, maintenance, training and provision of hyperbaric therapy.</p> <p>e) <i>Support personnel</i> - these include registered nurses, emergency service personnel and paramedics, who are trained and certified as competent to attend to patients inside and outside of the chamber.</p>
2.1.4	Personnel health & safety	Staff working within a hyperbaric unit may be subjected to specific occupational hazards including: a) Adverse reactions to disinfectants & cleaning solutions;	4	<p>a) The facility should maintain a long-term medical surveillance program with active monitoring of staff health and safety issues. Such a program should include entry, periodic & exit medical examinations.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
	Personnel health & safety (cont.)	<p>b) Risk of infection from patient-borne diseases; and</p> <p>c) Physical injuries (especially as a result of patient handling efforts).</p>	<p>4</p> <p>3</p>	<p>b) Any form of adverse reactions, conditions or illnesses should be investigated to determine if the cause is occupationally-related.</p> <p>c) Occupational health issues require specific reporting, monitoring and follow-up to comply with employment regulations. It is recommended that this service be outsourced to an independent occupational health provider.</p>
2.1.5	Responsibility	<p>The safety of a hyperbaric facility is affected by the conditions and practices in and around the unit and in the host health-care facility, if applicable. If responsibility for those conditions and practices is not clearly assigned, it can put the safety of the chamber at risk.</p>	<p>4</p> <p>4</p> <p>3</p> <p>3</p>	<p>a) The ultimate responsibility for the care and safety of patients and personnel lies with the health care facility's board. This board should thus ensure that safety, rules, practices and conduct throughout the facility are effectively and formally delegated to competent and responsible people.</p> <p>b) The hyperbaric facility Medical Director is responsible for the daily activities surrounding the facility. All personnel delegated with the responsibility of operating, administering, inspecting and maintaining the facility and all the associated equipment should be under the direct control of the appointed Medical Director.</p> <p>c) The Safety Officer should be responsible to both the Medical Director, as well as to the health care facility's safety committee regarding all equipment and related safety matters. However, the Medical Director should remain ultimately responsible as the "user" as defined under occupational health and safety regulations.</p> <p>d) In all cases, the medical staff should adopt and adhere to the professional regulations pertaining to the use of facilities located within formal health care facilities.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.1.6	Policies	Operational safety can be compromised where policies fail to integrate/account for the sometimes-conflicting requirements detailed in national, regional, and municipal statutes/regulations and in international guidelines and industry-specific equipment instructions (e.g., there can be variation in rules for the allowable oil-vapour content in compressed air or the allowable voltage in a confined space).	3	An integrated set of policies – mandating compliance with all applicable national, regional, and municipal statutes and regulations, especially those regarding the use of equipment – should be established and enforced by suitably competent and experienced personnel.
2.1.7	Operating procedures	Inadequate, unproven and non-formal operating and safety procedures can present a serious hazard to the safe operation of the hyperbaric facility. This is applicable to both normal operations as well as to emergency procedures.	3	Internationally accepted, qualified and well-proven procedures should be established, implemented and continuously monitored.
2.1.8	Implementation & compliance	Procedures that have not been correctly implemented nor adhered to, and staff that are not trained to understand and follow such procedures, will result in mistakes and oversights that will endanger the safety of both patients and staff.	5 3	a) The Medical Director is responsible for ensuring that all staff receive the appropriate and recognised training, adhere to operating and safety procedures, and are competent to fulfil their respective responsibilities effectively. b) The Medical Director should ensure that periodic audits of the effective functioning of the operating and safety management systems are conducted.
2.1.9	Regular operator inspections	If chamber operators fail to conduct regular pre- and post-treatment inspections of the chamber, risky situations could arise (e.g., patients taking hazardous items into the chamber, etc.).	4	A set of comprehensive pre- and posttreatment checklists should be established as part of the treatment log. This will ensure that the operator is reminded to perform the necessary safety, cleaning, and system checks before and after each and every treatment.
2.1.10	Patient transport and referral procedures	Failure to establish procedures for when and how a patient is transferred elsewhere could place the patient at risk and could open a facility to liability.	4	Procedures should be established regarding when and how to transport emergency cases to or from the healthcare facility, if the hyperbaric unit is not attached to a full-service medical facility. Free-standing or independent hyperbaric facilities should not undertake stabilization or extended care of emergency cases.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.1.11	Rules & regulations	A lack of adequate training, discipline, contingency planning, or adherence to procedures and/or a lack of sufficient responsible and trained staff represents a risk to the facility's patients and staff and to the facility itself.	<p>4</p> <p>5</p> <p>5</p> <p>5</p> <p>4</p> <p>5</p> <p>4</p>	<p>a) Clear rules and regulations for the operation of the facility, should be established through the Medical and Safety Officers.</p> <p>b) All staff should be thoroughly trained in the implementation of these rules and regulations. Such training should include regular follow-up sessions and hands-on training.</p> <p>c) Treatments should be performed only under the direct supervision of a medical doctor, with appropriate HBO training and experience.</p> <p>d) The operator should remain in attendance throughout every treatment, irrespective of any emergency that may occur.</p> <p>e) The Medical and Safety Officers should ensure that discipline is maintained at all times. They are also responsible for contingency planning and training.</p> <p>f) All staff should be thoroughly trained and experienced in the use of emergency equipment.</p> <p>g) The Medical Director should establish minimum staff qualifications, experience and levels based on the nature and size of the HBO facility, as well as the type of therapy normally provided.</p>
2.1.12	Required documentation	Proper documentation for all hyperbaric treatments is necessary to avoid the legal ramifications that could arise from delivering unauthorized, unsuitable, or ineffective treatments.	<p>4</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p>	<p>The following list covers the essential requirements for a hyperbaric treatment facility:</p> <p>a) Completed indemnity & acknowledgement forms</p> <p>b) Hyperbaric chamber operator checklist</p> <p>c) Patient records</p> <p>d) Patient treatment log</p> <p>e) Operational treatment log</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.2 General Requirements

2.2.1	Direct heat sources	The presence of open flames, smoking materials and/or heated objects represent a serious hazard in the operating environment.	5	Any object that could be a source of heat or UV radiation that could damage/degrade acrylic viewports should be specifically banned from hyperbaric facilities – either within the chamber or in its immediate outside vicinity. Sources of heat or UV radiation could also trigger the chamber’s fire detection system (if it has one).
2.2.2	Flammable gases & liquids	Flammable gases and liquids, especially with higher elevated oxygen levels, represent a serious risk of fire, even after the completion of treatments.	5 4	a) All flammable gases and liquids, including those contained in cigarette lighters and chemical hand warmers, are forbidden inside the chamber, as well as near the intake to the compressor(s). b) Alcohol-based pharmaceuticals may be permitted only if they are medically necessary; have been authorized by the health-care professional treating that specific patient; and have the specific consent of the facility’s Safety Officer. The quantities of such products should be limited to an extent such that only an insignificant amount of flammable vapour could be released into the chamber environment. In addition, all sources of electrostatic spark discharge should be eliminated.
2.2.3	Personnel	Overcrowding and the presence of superfluous personnel represent a risk to safe operations, as well as to the management of emergency situations.	3	Non-essential personnel should be kept out of the treatment areas. People accompanying patients should be restricted to formal waiting areas.
2.2.4	Porous Materials	Materials such as wood or clothing may retain oxygen for a significant period after treatment	3	Non-medical, porous or closed-cell materials should be excluded (or at least controlled) from being taken into the chamber.
2.2.5	Textiles & toiletries	Certain fabrics represent a serious risk in hyperbaric environments, especially in the event of a fire.	3	a) Procedures should be in place to ensure that patients wear only approved garments, fabricated of 100% cotton or an antistatic blend. Silk, wool and synthetic materials should be specifically banned.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
	Textiles & toiletries (cont.)	<p>For example, synthetic materials tend to retain oxygen in their closed-cell construction, and nylon undergarments can burn into the skin at high temperatures. Loose-fitting garments can incur the following risks:</p> <p>a) They can make it difficult to determine whether patients are carrying hazardous items with them;</p> <p>b) They can compromise the wearer's safety in the event of a fire because they may retain trapped gas, expose skin, and/or interfere with a deluge system's operation; and/or</p> <p>c) They can catch on equipment or protuberances.</p> <p>The use of fabrics such as blankets, sheets, or drapes in a chamber represents additional fuel in the event of a fire.</p> <p>Certain personal toiletries and cosmetics represent a risk of fire.</p>	<p>3</p> <p>4</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>4</p>	<p>b) Dedicated cotton garments, supplied by the facility to patients before treatments, are strongly recommended.</p> <p>c) Where patients are contaminated with oils or grease (such as accident victims), they should be cleaned before donning facility treatment garments.</p> <p>d) Wherever possible, all other fabrics should be treated with flame reducing compounds or be inherently flame-resistant.</p> <p>It is important to note that flame-retardant compounds often require regular reapplication, especially after washing. The instructions of the compound's manufacturer should be closely followed.</p> <p>e) Only antistatic materials should be used.</p> <p>f) Although most medical dressings do not pose a significant risk, substances such as petroleum jelly (Vaseline) and hook and loop fasteners (Velcro) should be avoided.</p> <p>The Medical Director should make any safety decisions in this regard.</p> <p>g) Garments should cover as much of the patient's skin as possible.</p> <p>h) Garments should either be supplied without pockets or pockets should be sewn shut, to reduce the risk of patients bringing hazardous items into the chamber.</p> <p>i) Where it is impractical to clothe some patients in such garments, only flame-resistant textiles should be permitted.</p> <p>j) Flammable hair sprays, hair oils, skin oils and cosmetics should be banned for all patients.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.3 Emergency Procedures

2.3.1	Procedures for emergency situations	<p>It is often not possible for operating and attending staff to react effectively in an emergency unless they have received adequate training and support.</p> <p>Emergencies may be operational or technical in nature, or may involve medical issues with either patients or staff.</p> <p>Medical issues with patients are addressed in 2.3.2 and with staff in 2.3.3 below.</p>	5	<p>It is imperative that every hyperbaric unit establish and document emergency procedures to: ensure the safe completion of treatments, the safe evacuation of patients and staff in the event of an emergency, and the effective handling of any potential emergency situation.</p> <p>The following are among the emergency situations that should be covered:</p> <ul style="list-style-type: none"> • loss of primary oxygen and/or air supply • loss of back-up oxygen and/or air supply • contamination of oxygen or air supply • rapid increase or decrease in chamber pressure • fire inside or outside the chamber • loss of power • failure of any chamber systems (communications, controls) • activation of room fire deluge system
2.3.2	Procedures for patient medical emergencies	<p>Medical emergencies must be dealt with promptly to avoid fatalities and to prevent disability resulting from injuries or diseases.</p>	5	<p>It is imperative that each hyperbaric unit establish and document emergency procedures to ensure that patient medical emergencies can be managed appropriately.</p> <p>The following are among the situations that should be covered:</p> <ul style="list-style-type: none"> • Oxygen toxicity • Arrhythmias, cardiac arrest (& defibrillation) • Pneumothorax • Barotrauma (middle ears, sinuses, teeth, lungs, intestinal) • Arterial gas embolism • Respiratory distress / bronchospasm • Suspected hypoglycaemia • Vomiting • Loss of consciousness • Claustrophobia

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.3.3	Procedures for medical emergencies in staff	<p>Medical emergencies in staff should be dealt with in a standardized manner to prevent illness or injury that could result in disability or render the staff member unable to manage occupants of the chamber.</p> <p>Occupational injuries and diseases carry an additional legal risk and emergency procedures should take into account any specific legal requirements that may apply</p>	5	<p>It is imperative that each hyperbaric unit establish and document emergency procedures to ensure that staff medical emergencies can be managed appropriately. Some “patient-procedures” will also apply to staff, but dedicated procedures should be available for:</p> <ul style="list-style-type: none"> • Sharps injury/infective fluid exposure • Occupational injury/occupational disease

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.4 Equipment

2.4.1	Approved equipment	The use of noncompliant or unapproved equipment, instruments, or devices represents a risk of explosion, implosion, and/or fire.	4	a) Only equipment that is specifically compliant with the requirements of this document, or that has been specifically approved for use within hyperbaric chambers, should be used. b) All other equipment is expressly prohibited from being taken into the chamber. This includes any high-energy devices, photographic flashes, lasers, tablets and cellular telephones .
2.4.2	Defective equipment	Defective equipment can compromise safety and hamper emergency responders.	5	Defective equipment, or equipment suspected of being defective, should be withdrawn from use and repaired to the satisfaction of the Safety Officer prior to being returned to the chamber.
2.4.3	Flammable items	Flammable (i.e., easily combustible) items and substances represent a risk of fire. These include, but are not limited to, paper, and lubricants.	4 4	a) Flammable items should be kept to an absolute minimum inside the hyperbaric chamber. b) Newspaper should be expressly prohibited, due to the volatile inks used by some papers.
2.4.4	Temperature ratings	Equipment with unsuitable temperature ratings can cause a fire or explosion.	5	All equipment intended for use in a chamber should strictly follow the chamber's temperature rating requirements. This matter requires particular vigilance by staff.
2.4.5	Oxygen equipment compatibility	Many items if ignited within a pressurised, oxygen-enriched atmosphere are not self-extinguishing.	4 3 3	a) Only approved, dedicated oxygen containers, control mechanisms, interconnecting hoses and fittings, valve-seat materials and lubricants should be used. b) International guides for determining the suitability of materials for oxygen compatibility should be followed. c) Static conditions and impact conditions are both applicable. ASTM and NFPA guidelines for design using oxygen-compatible materials should be followed.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.4.6	Oxygen cleaning procedures	Contamination of oxygen equipment presents risk of fire or explosion.	3	Oxygen equipment, including fittings, connections, gas handling equipment, etc. should be oxygen cleaned prior to use. Oxygen cleaning requires special considerations and only approved procedures should be used.
2.4.7	Oxygen lubricants	HC lubricants are a known source of fuel in an oxygen-enriched environment.	4	Only oxygen compatible lubricants should be used inside the hyperbaric chamber.
<p><i>Caution: Certain sealed equipment, for example Tycos™ pressure bags, contains hydrocarbon-based lubricants that are unacceptable. Special oxygen compatible lubricated units are available from Tycos™.</i></p>				
2.4.8	Light metals	Light metals such as cerium, magnesium and magnesium alloys are all capable of burning in oxygen or compressed air.	5	All combustible light metals are prohibited from being used within a hyperbaric chamber.
2.4.9	Radiation exposure	X-rays or gamma radiation can degrade acrylic windows. This risk is especially applicable if the source of radiation is located outside the chamber and the radiography is delivered through the viewport.	4	a) If acrylic windows will be exposed to any form of high-energy radiation, facility owners and managers should be aware that the service life of the window will be drastically reduced. The maximum allowed absorbed dose is 40 kilo gray (kGy) (4 mega rad [Mrad]). Exposure to X-rays or gamma radiation reduces window service life to three years.
		Direct sunlight is also a known source of harmful UV and infrared radiation capable of degrading acrylic viewports.	3	b) Exposure to harmful UV or infrared radiation (e.g., from direct sunlight) also reduces the service life of acrylic viewports. In such cases, ASME PVHO-2 requires strict adherence to a maximum service life of 10 years.

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Ref.	Element	Risks	RL	Minimum Requirement
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2.5 Handling of Gases

2.5.1	Compressed Gas Standards	The storage and handling of compressed gases, and the installation and cleaning of oxygen and related piping systems, involve serious risk of fire and/or explosion.	3 3 3	<p>a) The CGA Handbook of Compressed Gases provides minimum safety guidelines. The sections relevant to the storage and handling of all gases (e.g., compressed air, oxygen, nitrogen) should be followed by all hyperbaric facilities.</p> <p>b) CGA G-4.1, Cleaning Equipment for Oxygen Service, provides minimum safety guidelines for cleaning oxygen piping systems. Either this document or a suitable alternative deemed appropriate by the <i>Safety Officer</i> should be followed in full.</p> <p>c) ASTM G-93-96, Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen-Enriched Environments, provides further guidance on cleaning oxygen piping systems.</p>
2.5.2	Procedures for handling gases	Handling of compressed gases represents a risk of both fire and HP explosion.	4	Only qualified staff is permitted to operate or work on gas handling equipment.
2.5.3	Liquid oxygen storage	<p>Liquid oxygen contains a great capacity to support combustion.</p> <p>Porous materials (wood & clothing) retain oxygen for significant periods after exposure.</p> <p>Organic and hydrocarbon-based materials are potential hazardous in oxygen environments.</p> <p>Liquefied gases boil off rapidly and can change the oxygen composition of the surrounding atmosphere.</p>	5	<p>Storage containers require at least the following considerations:</p> <ul style="list-style-type: none"> • Porous materials should be kept to a minimum, and due care exercised after exposure to oxygen. • Organic, asphalt and petroleum products should not be used in oxygen storage areas. Cryogenic storage tanks should be mounted on gravel or concrete bases and not asphalt (tar). • Undergrowth, shrubs and grass should be cleared for at least 3 m (10 ft) around the storage areas. • Storage areas should be fenced off and secured against unauthorised access. • Liquid oxygen piping should be insulated. • Warning signs (including No Smoking and Danger) should be posted.
2.5.4	Flammable gases	Flammable gases represent a severe risk of fire.	4	No flammable gases should be stored in or near the hyperbaric facility, or near any compressor intake(s).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.5.5	Stored gases	Large quantities of stored gas, especially oxygen, elevate the risk in the event of a fire, especially if the storage containers are not regularly inspected for leaks. Pressurized containers also represent a risk of explosion.	3 3	The amount of oxygen stored in or around the hyperbaric facility should be kept to the minimum required to complete treatments, and to deal with emergency situations. Pressurised containers should only be taken into the hyperbaric chamber where they are approved for use.
2.5.6	Use of non-flammable gases	Even nonflammable pressurized gases present risks unless sufficient control systems are in place.	3	Nonflammable gases required for use in a chamber should be piped into the facility. Shutoff valves accessible to staff members should be located at the points of entry to the room housing the chamber.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.6 Maintenance

2.6.1	Regular testing & calibration of equipment	Inadequate maintenance of oxygen-handling equipment, chamber controls, and safety equipment can result in equipment failure, representing risks for both operators and patients.	3 3	a) The Safety Officer should be responsible for ensuring that all equipment is regularly checked and serviced. b) Pressure relief valves, gauges and analysers require regular calibration.
2.6.2	Labelling of gas outlets	Inadequate labeling of oxygen-system components, especially outlets, risks their not being identified during emergencies.	3	All essential controls on an oxygen system, especially gas outlets, should be clearly labeled. It is also imperative that the gases delivered at every labeled outlet are checked prior to their first use (by reviewing the attached certificate[s] of analysis or, preferably, by online gas analysis).
2.6.3	Replacement parts	The use of non-specified spares and replacement parts may result in premature equipment failure.	3	The Safety Officer should be responsible for ensuring that only manufacturer-authorized components are used both during initial installation and during subsequent maintenance of all equipment.
2.6.4	Authorised work	All installation, repair and modification work to hyperbaric chambers and their associated equipment directly affects the safe function of the facility.	3 3	a) The Safety Officer should ensure that only <i>competent personnel</i> perform repair and maintenance work according to the provisions of both legal requirements and equipment manufacturer's manuals. b) All equipment should then be fully tested, and the results logged after any repair or maintenance work is performed.
2.6.5	Maintenance logs	A lack of operating and/or maintenance logs precludes adequate control of maintenance procedures, potentially resulting in premature equipment failure.	2	The Safety Officer should ensure that logs of all operating and maintenance procedures are maintained and correctly certified by either the maintenance technicians or the Safety Officer.
2.6.6	Cleaning of filters	Blocked or partially blocked filters reduce efficiency of chamber operation, provide a risk where rapid decompression may be required, and may introduce dirt and contaminants should filters fail as a result of excessive loading.	3 3 3	a) The chamber gas supply inlet filters should be cleaned or changed at least annually. b) Inlet filters for regulators, flow controls and the exhaust system similarly require annual maintenance. c) Manufacturers' recommendations should be adhered to at all times.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
	System maintenance (cont.)		3	c) A documented corrective maintenance system should be in place. This should include the full cause-and-effect recording of all system failures and break-downs; logging of corrective actions; placing of “holds” on further manned pressurisation excursions until resolved and approved by the Safety Officer; and regular audits by the Safety Officer.
			3	d) A suitable, dedicated maintenance area, equipped with dedicated tools and instruments, is required to enable personnel to affect repairs, replacement and cleaning with minimum “downtime”.
2.6.8	System cleaning procedures	<p>Ineffective or incomplete cleaning of hyperbaric piping and gas storage systems can introduce dangerous substances into the systems, posing a risk of fire or toxic contamination.</p> <p>A failure to thoroughly clean chambers and their associated equipment on a daily basis can result in the spread of transmissible diseases.</p>	3	a) After initial installation of any gas supply or control systems – or after any repairs, additions, or modifications to such systems – a cleanliness certificate should be issued that meets the satisfaction of the Safety Officer
			3	b) Suitable cleaning procedures should be documented and should be certified as effective by the Safety Officer prior to being implemented. These procedures should preferably include objective inspection and testing instructions.
			3	c) Suitable, noncorrosive antiseptics and detergents should be used to clean all surfaces at the end of every treatment day.
			4	d) Caution is required in cleaning certain components (e.g., viewports and fire-resistant bedding and mattresses) to avoid degradation of the material or a reduction in its fire-resistant properties.
			3	e) Safe and comprehensive protocols should be established regarding issues such as protective clothing, disposal of cleaning containers, disposal or cleaning of contaminated linens, inspection of chambers after they have been cleaned, and adequate ventilation both during cleaning and prior to treatments.

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Ref.	Element	Risks	RL	Minimum Requirement
	<p><i>Warning: Trichloroethylene is not recommended as a cleaning compound in hyperbaric chambers. Apart from personnel hazards, the fluid reacts with CO₂ absorbent chemicals forming a toxic, volatile and even explosive compound.</i></p>			
2.6.9	Approved lubricants or consumable materials	Many common and accepted lubricants and consumable materials are not safe for use within a hyperbaric environment, especially in the presence of high concentrations of oxygen.	4	<p>a) The criteria by which materials are judged safe for use in a hyperbaric environment should include the following:</p> <ul style="list-style-type: none"> • Suitably pressure-rated and oxygen-compatible; • Nontoxic; • Nonreactive with system elastomers and other similar materials; • Noncorrosive; and • Effective and easy to apply or use. <p>2 b) Materials should be clearly identified for their intended use and should be packaged to keep out contaminants.</p> <p>2 c) Lubricants should be used sparingly and should not be used to correct equipment flaws (e.g., on nonsealing joining surfaces or to compensate for a poor fit). All excess lubricants should be removed prior to the use of the equipment.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.7 Electrical Safeguards

2.7.1	Testing	Any electrical faults or failures of a chamber's protective equipment presents considerable risk to the safety of the operating environment.	4	All electrical circuits, ground fault interrupters (GFIs), and line insulation monitors (LIMs) should be tested before each treatment session, to assure that they are functioning normally and that no live conductors are grounded.
2.7.2	De-energizing equipment	A failure to de-energize electrical equipment during a fire, especially in facilities with a sprinkler or deluge system, can be exceedingly dangerous, due to the risk of electrical shock and even death if water comes in contact with an electrical fire.	4	Any electrical equipment either in or attached to the chamber that is not life-critical should be de-energized prior to the activation of a sprinkler or deluge system (unless it is adequately waterproofed).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.8 Electrostatic and General Safeguards

2.8.1	Electrostatic sparks	<p>Electrostatic discharge may present a potential ignition source, may disrupt electrical monitoring equipment and is a source of discomfort for chamber patients.</p> <p>In addition to the potential sources of static generation from equipment or materials, a patient moving normally inside a (dry) chamber may build a static charge.</p>	3 3	<p>a) The elimination of static charges requires the vigilance of all operating personnel, control of materials purchased, maintenance, periodic inspection and testing, and the constant awareness of sources.</p> <p>b) Patients should be grounded to a metallic non-moving, permanently grounded part of the chamber using a suitable grounding device, prior to the door being closed.</p>
2.8.2	Conductive flooring	In dry locations, unsuitable, ungrounded flooring materials may build static charges.	2	Conductive flooring as pertaining to anaesthetizing locations within health care facilities should apply where needed.
2.8.3	Fixtures and internally located, non-fixed equipment	<p>Inadequate grounding, loose conductive fixtures and materials could hinder effective grounding inside the chamber.</p> <p>Impact, high temperature sparking may occur where ferrous containing parts and aluminium surfaces are used in areas of with high-loading.</p>	3 3 4 3 3	<p>a) Periodic inspection of the integrity of joints, grounding and insulation by loose foreign materials should be conducted.</p> <p>b) Movement of fixtures should be avoided during treatments.</p> <p>c) Metals exhibiting impact-sparking potential should not be used in high loading areas.</p> <p>d) Accessories such as sheets, plastic covers, rubber accessories, etc. should be selected on the basis of reduced conductivity or antistatic properties.</p> <p>e) Casters and bearings inside the chamber should be regularly inspected, cleaned and lubricated using oxygen-compatible, conductive lubricants.</p>
2.8.4	Materials containing rubber	Rubber materials deteriorate rapidly in an oxygen-enriched environment, resulting in reduced mechanical strength.	3	All rubber-bearing materials should be regularly tested, in accordance with established periodic maintenance requirements, especially at points of kinking. This is especially applicable to rubber with a high carbon content.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.9 Housekeeping

2.9.1	Tidiness	Cluttered and untidy facilities present a safety hazard in terms of operational control, especially during emergency situations.	3	The Medical Director should ensure that operating areas are kept free of unnecessary equipment, that non-essential equipment is stowed away, and that essential equipment is at hand.
2.9.2	Cleanliness	A build-up of flammable materials, such as grease, dirt, lint and dust, represents a fire hazard.	3	a) It is essential that the hyperbaric chamber be kept meticulously free of all greases, lint, dirt, dust and undesirable materials.
			3	b) The person tasked with daily cleaning should be thoroughly briefed as to the dangers of uncleanliness.
2.9.3	Diseases & contamination	The lack of, or inadequate, daily cleaning of the chamber and equipment may cause transmission of diseases and spread of contamination.	3	a) A suitable, non-corrosive, antiseptic (e.g., quaternary ammonia-based) and synthetic (e.g. non-soap detergent) should be used to clean all surfaces following each treatment day.
			3	b) Due caution is required in cleaning certain hyperbaric components, viz. fire-treated bedding and mattresses, to avoid degradation or a reduction in fire-resistant properties.
			3	c) Safe and effective protocols should address issues such as protective clothing, disposal of cleaning containers, disposal or cleaning of contaminated linen, inspection of chamber after cleaning, and adequate ventilation both during cleaning as well as prior to treatments.
2.9.4	Acrylic cleaning procedures	Acrylic materials are sensitive to: <ul style="list-style-type: none"> ▪ Abrasion - reducing visibility; ▪ Surface damage - reducing life span; and ▪ Degradation due to chemical incompatibility, all potentially reducing both visibility and life span. 	4	a) Antiseptic and cleaning compounds should be specifically certified as being suitable for acrylic viewports.
			3	b) Due caution is required in cleaning acrylic components to avoid mechanical damage.
			3	c) A soft, lint-free cloth should be used to clean the acrylic viewport.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
2.9.5	Standby conditions	Standby periods generally imply less attention to housekeeping, with the attendant danger of non-compliance with facility safety procedures.	3	<ul style="list-style-type: none"> • Chambers should be kept covered with the doors closed when not in use. • Heavy items should not be stored above chambers to avoid impact damage if disturbed or allowed to fall. • Only properly trained personnel should be allowed to clean the facility. • The entry of unauthorised personnel into the facility should be prevented. • The facility should preferably be kept secured (locked) at all times.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.10 Medical Staff Training, Qualifications, Registration and Affiliations

	<p><i>Comment: All hyperbaric health care providers should have the necessary and appropriate training and skills to deliver hyperbaric therapy in a safe, appropriate and ethical manner.</i></p> <p><i>Monoplace chamber operators may be persons who are not licensed medical personnel when non-critical patients are being treated. Different regulatory requirements might apply in specific areas.</i></p> <p><i>However, medical practitioners and licensed medical personnel should always be involved in patient treatment and a medical practitioner should be immediately available during patient treatments.</i></p> <p><i>Increased legal liability risks exist where chamber staff are not professionally registered, as is appropriate.</i></p>			
2.10.1	HBO medical practitioner	<p>The ability to administer and monitor hyperbaric medical treatments requires specific knowledge, training and experience.</p> <p>Patients may present with a range of responses and side effects.</p> <p>Numerous other medical complications and situations may also arise.</p> <p>The sealed pressure vessel housing the patients restricts the practitioner to managing the situation in a hands-off manner.</p>	4	<p>The HBO medical practitioner should hold the following minimum qualifications and registration:</p> <ul style="list-style-type: none"> • Registration with a State or applicable board as a medical practitioner • Hyperbaric medicine training, as endorsed by the national hyperbaric medical association - refer also to 2.10.4 below. • Current BLS training (ACLS training is strongly recommended).
2.10.2	Hyperbaric nurse	<p>Nurses are also employed to administer and monitor hyperbaric medical treatments.</p> <p>Nurses require specific knowledge, training and experience.</p> <p>Patients may present with a range of responses and side effects.</p> <p>Numerous other medical complications and situations may also arise.</p> <p>The sealed pressure vessel housing the patients restricts the nurse to managing the situation in a hands-off manner.</p>	4	<p>The hyperbaric nurse should hold the following minimum qualifications and registration:</p> <ul style="list-style-type: none"> • Registration/licensure as a registered nurse • Hyperbaric nursing training, as endorsed by the national hyperbaric medical association - refer also to 2.10.4 below. • Current BLS training (ACLS training is recommended). • Membership of the national hyperbaric medical association as either a hyperbaric nurse, technician or an associate member.

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Ref.	Element	Risks	RL	Minimum Requirement
2.10.3	Chamber operators	Medical complications and emergencies require specific operational actions to mitigate additional risks and exposure to patients.	4	<p>Appropriate knowledge, training and experience are required for the operator to be able to make decisions regarding pressure control, ventilation, monitoring and termination of treatment.</p> <p>The person operating the hyperbaric chamber should be a suitably qualified chamber operator with:</p> <ul style="list-style-type: none"> • Appropriate training, as endorsed by the national hyperbaric medical association - refer also to 2.10.4 below. • Membership of the national hyperbaric medical association as either a hyperbaric technician or an associate member.
2.10.4	National hyperbaric medical association	Current practices, cautions, dangers and remedial actions are made available to the HBO industry through national hyperbaric medical associations.	3	All persons involved in patient care should be current members of a recognized association or its affiliate organisation (e.g., UHMS, EUBS, SPUMS, HTNA, AHDMA, SAUHMA).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.11 Patient Care

2.11.1	Staffing levels	Chamber operations and patient complications are complex, under normal as well as emergency conditions, and thus requires a minimum complement of qualified staff.	4	<p>The following minimum staffing levels should be maintained at all times:</p> <ul style="list-style-type: none"> • The chamber operator • The HBO medical practitioner who is qualified to deliver hyperbaric oxygen therapy. <p>No chamber should be left without an operator in control at any point, even in the event of a medical or other emergency that affects the delegated operator.</p>
2.11.2	Visual contact	Without early and appropriate diagnosis of imminent medical complications, especially those related to patients under hyperbaric pressure, the required response and/or treatment to a patient in distress could be delayed.	4	<p>The chamber operator should have full visual access of the patient at all times.</p> <p>Medically qualified personnel (i.e., the HBO medical practitioner - or hyperbaric nurse practitioner) should be able to have a direct line of vision to patients being treated.</p>
2.11.3	Medical supervision	<p>Professional expertise is required to deal with the side effects and complications of treatments and with the possibility that advanced care, life-support services, or complicated interventions might be required.</p> <p>Failure to provide proper medical supervision can thus compromise a patient's health or life.</p>	3	<p>A qualified HBO medicine practitioner should be available at all times during all treatments and should supervise treatments in accordance with international requirements for medical supervision.</p> <p>This is especially applicable if the chamber operator is not registered with a professional medical board.</p>
2.11.4	Patient medical screening	<p>Significant physiological risks exist for patients with contraindications if they are placed under hyperbaric pressure, especially if they are also administered oxygen-enriched gases.</p> <p>Patients may also have psychological and/or social issues that can affect their health and safety and/or the outcome of their treatments.</p>	4	<p>Every patient should be screened by a qualified HBO medicine practitioner before being accepted for treatment.</p> <p>The screening should include confirmation of the appropriateness of the treatment, the lack of any contraindications, and an assessment of the patient's physical and psychological status.</p>

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Ref.	Element	Risks	RL	Minimum Requirement
2.11.5	Patient selection	<p>The inappropriate use of HBO may result in the refusal of reimbursement and the applicable authorities to accept the specific treatment modality.</p> <p>Patients may be subjected to unnecessary risks where HBO is not essentially required.</p>	2	<p>Patients should be selected for HBO treatment in accordance with the national hyperbaric medical association-approved guidelines, including the use of transcutaneous oximetry and other approved assessment tools.</p>
2.11.6	Patient orientation	<p>Patients who are unaware of the hazards associated with HBO treatment could inadvertently bring prohibited items or materials into a chamber.</p> <p>If patients are not well informed about the process, they may experience anxiety which could cause them to panic or at the least experience additional stress.</p>	3	<p>Patients should receive an orientation to the HBO facility, as well as to all relevant policies and procedures, before their treatment begins.</p> <p>The orientation should emphasize safety precautions related to fire and pressure hazards (e.g., prohibited items and materials).</p>
2.11.7	Acknowledgement of safety precautions	<p>Patients may not necessarily comprehend the impact of safety precautions due to ill health or infirmity.</p>	3	<p>Acknowledgement of safety precautions should be given by patient or their legal guardian in the written form.</p>
2.11.8	Written and informed consent	<p>It is extremely difficult to prove consent by or on behalf of a patient without a written record.</p> <p>It is also extremely difficult to prove that a patient fully comprehended the hazards and the impact of safety precautions at the time of consenting unless a fully and bilateral discussion is held with or on behalf of them.</p>	3	<p>Written informed consent should be obtained from each patient (or the legal guardian) and such written consent should be kept available in each patient's medical file.</p> <p>Before obtaining informed consent for hyperbaric treatment, the risks, benefits, and potential complications associated with hyperbaric treatment should be discussed with the hyperbaric patient or legal guardian.</p>
2.11.9	Patient care & treatment plan	<p>In order to ensure compliance with medical practices, all treatments need to be planned and documented prior to commencement of treatment.</p>	3	<p>The HBO medical practitioner should develop and prescribe a plan of hyperbaric care and this should be documented in the patient's medical record before hyperbaric treatment is initiated.</p>
2.11.10	Patient privacy	<p>Infringement of patient privacy rights may lead to legal actions against facility staff.</p>	3	<p>Hyperbaric-associated patient care procedures (such as wound care) should be performed in a manner that respects privacy.</p>

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Ref.	Element	Risks	RL	Minimum Requirement
2.11.11	Infection control	<p>It is difficult to assure proper infection control within the confined nature of a hyperbaric chamber, as well as the specialised handling equipment.</p> <p>Chambers may be used with several patients, between daily cleaning routines, potentially leading to the spread of infections.</p>	<p>3</p> <p>3</p>	<p>a) Procedures should be in place to ensure that cross-contamination from one patient to another, and between patients and personnel, is prevented.</p> <p>This includes the use of appropriate decontamination procedures.</p> <p>b) Treatments of highly infectious patients may be scheduled for the last treatment of the day</p>
2.11.12	Patient records & procedures	<p>Failure to comply with national requirements regarding patient records can put a facility in legal jeopardy.</p>	3	<p>Patient medical records should be kept up to date and confidential, with individual files kept on each patient.</p> <p>Any relevant national regulations regarding patient records should be followed.</p>
2.11.13	Minimum medical emergency equipment available	<p>If a patient experiences distress while in the chamber, it may be necessary to render immediate care either inside the chamber or immediately upon extracting the patient from the chamber. Some HBO facilities do not have ready access to hospital emergency departments.</p> <p>The lack of equipment to handle such situations can compromise patients' health or life.</p>	3	<p>Medical equipment suitable to handle any foreseeable emergencies, consistent with the facility's advertised scope of services, should be available, maintained, and readily accessible.</p> <p>The following medical equipment is recommended to deal with foreseeable emergencies (inside and/or outside the chamber):</p> <ul style="list-style-type: none"> • Intercostal drainage set; • Defibrillation; • Airways & ET tubes; • Intravenous fluids; • Glucose for injection; • Monitoring (at least ECG, blood pressure, oxygen saturation, temperature); • Self-re-inflating bag for artificial ventilation (e.g., Ambu-bag) with oxygen inlet; and • System for providing normobaric oxygen
2.11.14	Availability & control of medical emergency equipment	<p>Based on the potential for irregular and infrequent use, medical equipment may be neglected before being noticed.</p>	3	<p>Medical emergency equipment enlisted in the 2.11.13 should be consistently available, controlled, and secure in the hyperbaric treatment area.</p>
2.11.15	Continuity of treatment	<p>The condition of the patient is very dependent on the continuity of essential, relevant treatments.</p>	3	<p>For every patient, continuity of treatment, including oral and intravenous medications, surgical procedures and diagnostic tests should be ensured.</p>

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Ref.	Element	Risks	RL	Minimum Requirement
2.11.16	Short-term results of HBO treatments	Comprehensive information on patient response to treatment is required in order to provide a sound basis for ongoing treatments, or the cessation of treatment, where relevant.	3	For every patient, the short-term results of HBO treatment should be recorded in the patient's medical record along with appropriate objective evidence (e.g., pictures of wound, level of carboxyhaemoglobin).
2.11.17	Long-term results (follow-up) of HBO treatments	The long-term sustainability of HBO for the entire industry rests upon solid medical evidence of the efficacy of HBO for specified conditions.	2	Procedures should be implemented to monitor the long-term effects of HBO treatment (i.e., follow-up) for as many patients as possible.
2.11.18	Alert data	Immediate and appropriate reactions are required in order to deal with patients suffering from identified, potentially complicating conditions.	4	Appropriate, specific management procedures should be in place for patients presenting with alert data (e.g., allergic reactions, diabetes mellitus, implanted cardioverters/defibrillators, movement restrictions, etc).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.12 Nursing Care and Interventions

2.12.1	Nursing care policies & procedures	<p>Nursing is a comprehensive and wide-spread occupation, and nurses are responsible for several, different operations within the HBO unit.</p> <p>Without specified and documented procedures, medical review assessments may not pick up on gaps or inadequate interventions until too late to remedy (such as in the event of an unforeseen situation).</p>	3	<p>Written nursing policies and interventions should be developed that address the following:</p> <ul style="list-style-type: none"> • Confinement anxiety/claustrophobia • Pain related to medical or surgical problems • Infection control • Discomfort related to temperature and humidity changes inside the chamber • The potential for ineffective individual coping related to the stresses of illness and/or poor psychosocial support systems • The potential for fluid volume deficit related to dehydration or fluid shifts • The potential for alteration in comfort, fluid and electrolyte balance related to nausea and vomiting • Wound care for patients with wounds • Prevention of pressure ulcers/ wounds • Safety inside the hyperbaric chamber • Management of alert data: defined in ref. 2.11.18.
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2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.13 Medicine and Medication Control

2.13.1	Medicine dispensing	Legal requirements need to be met with regard to the dispensing of any medications.	3	Preparing and dispensing medication(s) should adhere to legal, regulatory, licensing and professional standards of practice.
2.13.2	Control of dispensed medication	Untrained and unqualified personnel may not be aware of the full ramifications of the inappropriate administering of medication.	3	Preparation and dispensing of medication(s) should be appropriately controlled.
2.13.3	Minimum emergency medicine	The lack or unavailability of essential emergency medicines may result in the significant compromising of patients and even staff.	4	<p>The recommended emergency medicines that should be kept in the unit include the following (or equivalent):</p> <ul style="list-style-type: none"> • Adrenaline • Atropine • Glucose • Lignocaine (if indicated in the ACLS handbook) • Amiodarone (if indicated in the ACLS handbook) • Anticonvulsant • sedatives/anxiolytics • Aspirin • Nitrates (e.g., Angised) • Bronchodilators • Analgesics • Portable/ wall oxygen • Morphine • Furosemide • Anti-emetics <p>Medication may be combined (e.g., Midazolam used as anticonvulsant/sedative)</p>
2.13.4	Availability & control of emergency medicine	Based on the potential for irregular and infrequent use, emergency medicines may be neglected, allowed to expire, be removed or depleted or not retained in the specified location.	3	Emergency medications should be consistently available, controlled, and secured in the hyperbaric treatment area. A checklist with signatures may be used.
2.13.5	Management of scheduled medication	Staff may abuse scheduled medicine, leading to dependency and/or the inability to manage patients appropriately.	4	Scheduled medication should be managed in accordance with the regulations pertaining to the keeping of registers and safekeeping of the medication

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Ref.	Element	Risks	RL	Minimum Requirement
2.13.6	Medical waste management	Legal requirements exist with regards to the safe disposal of medical waste, so that no infectious risk exists to persons or the environment.	4	Medical waste management should conform to the appropriate regulations for hazardous biological agents.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirement
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2.14 Indications and Treatments Provided

2.14.1	Approved indications	All medical services are carefully scrutinised by national regulatory authorities and professional boards. Legal liability exists where ethical practices are transgressed.	3	Ethical practice should prevail, and HBO be provided for indications approved by the national hyperbaric medical association. Non-approved indications should be subjected to peer-review processes.
2.14.2	Treatment protocols	Treatment risks exist where internationally accepted and proven protocols are not followed.	3	Industry-accepted treatment protocols should be used for the treatment of patients, for example: UHMS, USN, Comex, the national hyperbaric medical association, etc.
2.14.3	Level of care capacity & patient selection	Unless the scope of available services is carefully defined and managed, based on expertise, equipment capability and availability, facilities may have patients they are not equipped to deal with.	3 3 3	a) A specific patient selection policy should be in place, including risk-benefit considerations. b) The level of equipment, monitoring and staff experience should be considered in these policies. c) Transfer and transport issues of critically ill patients to and from the facility should be addressed.
2.14.4	Relative & absolute contraindications	While contraindications for HBO treatments are known, facilities may not be aware of the full spectrum as well as the conditions under which these apply.	4	The list of relative and absolute contraindications separately for both elective HBO treatment for chronic indications and emergency HBO treatment for life-treating indications should be in place.

Concluding Remarks

This Guide represents a compilation based on relevant, available reference material related to the installation, commissioning, operation and possible modification or upgrading of a monoplace hyperbaric chamber facility.

While every effort has been made to provide a thorough assessment, additional hazards may be identified with time. The same is true for the NFPA 99 publication, which is also in a state of continuous improvement. As new information becomes available from the HBO facilities operated worldwide, additional measures to reduce hazards may be introduced.

The author and compiler of this guide acknowledges that much of the information used has been cited or extracted from the referenced publications and further acknowledges that to the best of his professional abilities, no obvious area of risk has been left unaddressed.

Abbreviations

A	ampere
ABS	American Bureau of Shipping
AC	alternating (electrical) current
acfm	actual cubic feet per minute
ACLS	Advanced Cardiac Life Support
AHDMA	Asian Hyperbaric and Diving Medical Association
AS/NZS	Australian/New Zealand Standard
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
ATA	atmosphere absolute, a unit of pressure, with 1 ATA being 101,325 kPa (14.7 psi) at sea level
atm	atmosphere gauge, a unit of pressure with 0 atm being the atmospheric pressure at sea level
BIBS	Built-In Breathing System
BLS	Basic Life Support
BNA	Baromedical Nurses Association
CO ₂	carbon dioxide
CO	carbon monoxide
°C	degrees Celsius (temperature)
CGA	Compressed Gas Association
cf	cubic foot or ft ³
CH ₄	methane
dB(A)	A-weighted decibel (a measure of sound as it's perceived by the human ear)
DC	direct (electrical) current
DT	dew point (frost) temperature (at standard atmospheric pressure and temperature)
EBAss	European Baromedical Association
ECHM	European Committee for Hyperbaric Medicine
EIGA	European Industrial Gas Association
EUBS	European Undersea & Baromedical Society
°F	degrees Fahrenheit (temperature)
ft	foot
gal	gallon (Imperial: 1 gal = 3.8 litres)
GFI	Ground Fault Interrupter (also ground fault circuit interrupter; detects current leakage to ground)
H ₂ O	water (moisture in vapour form)
HBO	hyperbaric oxygen (therapy)
HC	hydrocarbons (in liquid form)
HP	high pressure (assumed as > 1 MPa/150 psi for air and inert gases; > 0.86 MPa/125 psi for O ₂)
HTNA	Hyperbaric Technicians and Nurses Association
IPS	isolated power supply (also referred to as an isolated power system; provides electrical isolation between input and output circuits, and also provides separate ground paths)
kHz	kilo Hertz, a unit of frequency, also 1,000 cycles per second
LIM	line isolation monitor (also line insulation monitor; used to detect ground faults in ungrounded electrical systems)
LOX	liquid oxygen

LP	low pressure (assumed as < 1 MPa/150 psi for air and inert gases; < 0.86 MPa/125 psi for O ₂)
lpm	litres per minute, a metric unit of flow
LR	Lloyd's Register
MGy	mega gray (a unit of absorbed radiation dose, defined as 1 Joule/kilogram: MGy = 1 MJ/kg)
MPa	megapascal
Mrad	mega rad, unit of absorbed radiation dose, with 1 rad = 0.01 Gy
m	meter
µm	micrometer or 10 ⁻⁶ m, a unit of size
mA	milliampere
mg/m ³	milligrams per cubic meter (0.001 g/m ³)
mm	millimeter
mW	milliwatt
min	minute
nm	nanometer or 10 ⁻⁹ m, a unit of size
NBDHMT	National Board of Diving and Hyperbaric Medical Technology
NFPA	National Fire Protection Association
OCA	Oxygen Compatible Air
O ₂	oxygen
Pa	pascal
ppm _v	parts per million by volume ratio (also mole ratio)
psi	pounds per square inch - a measure of pressure (also psig)
PVHO	Pressure Vessels for Human Occupancy
RCD	Residual Current Device (detects current leakage to ground; provides similar protection as a GFI)
RL	Risk Level
SAUHMA	Southern African Undersea and Hyperbaric Association
scfm	standard cubic feet per minute, a unit of flow
SEV	surface equivalent value (expressed in percentage or %)
SPUMS	South Pacific Undersea Medicine Society
UV	ultraviolet light - light spectrum immediately below visible light, wavelength range 100 - 400 nm
UHMS	Undersea & Hyperbaric Medical Society
USN	United States Navy
USP	U.S. Pharmacopoeia
V _{AC}	volts alternating current
V _{DC}	volts direct current
V _{rms}	root mean square voltage
W	watt

Appendix A

Determination of Risk Levels

As referred to in the explanatory notes, a *risk* may be quantified by the product of the *probability* of an accident (i.e., the likelihood of occurrence), the frequency of *exposure* to the hazard (where it applies), and the *severity* (i.e., potential negative consequences) of an accident that might occur.

In all cases, a realistic assessment should be made of the actual quantification of each of the three elements: a realistic worst-case scenario should be considered as to the severity.

The Likert scale provides a suitable means of allocating scores to each element; the probability of fire, mechanical or health risks should be considered for each hazard assessed.

A score is thus computed as the product of each of the three elements. Ex: 5 x 5 x 5, or 125, being the highest score.

The three tables immediately below provide relevant descriptions for the quantification of probability, frequency of exposure and severity.

Probability/likelihood of an event (incident or accident) occurring					
Fire and explosion		Mechanical hazards		Physiological & Medical Hazards	
Combustion definite	5	Failure definite	5	Event definite	5
Combustion expected	4	Failure expected	4	Event expected	4
Combustion possible	3	Failure possible	3	Event possible	3
Combustion unusual	2	Failure unusual	2	Event unusual	2
Combustion unlikely	1	Failure unlikely	1	Event unlikely	1

Exposure to the hazard		Severity of the outcome	
Continuous: an entire shift	5	Catastrophic: e.g., death; life-threatening injury; destruction	5
Daily: < say twice a day	4	Severe: e.g., significant injury; facility no longer available	4
Weekly: < twice a week	3	Serious: e.g., reduced ability to treat/treatment quality	3
Monthly: < twice a month	2	Significant: e.g., minor damage/injury; additional staff needed	2
Annually: < twice a year	1	Noticeable: e.g., inconvenience; additional work required	1

It is possible to have no exposure to a hazard, or no consequences. In either case there is no risk.

Where a risk includes more than one of the probability risk categories (fire and explosion, mechanical hazards or physiological & medical hazards), each should be assessed separately (probability x exposure x severity) and the highest score used.

The next table provides empirically-derived guidance to the determination of a risk level, based on scoring probability, exposure and consequence, the associated risk rating, and requirement for mitigation based on urgency to avoid consequence.

Score	RL	Risk Rating	Requirement
> 100	5	Very high	Attention and risk mitigation are critical and must be given highest priority. A potentially dangerous situation may exist, with the possibility of very serious/catastrophic consequences in the event of an incident. The treatment activity should stop immediately and should not recommence until effective mitigation is in place.
60 - 99	4	High	Attention and risk mitigation are required and must be given high priority. A serious situation may exist that could endanger people or equipment or could seriously disrupt or jeopardize the business. Various solutions or actions may mitigate the risk, considered at the discretion of the <i>Safety Officer</i> , but they should be recorded in writing.
20 - 59	3	Medium	Attention is required. Eventual exposure to this risk could likely result in an incident. At the very least, outcomes may include business disruption, financial or liability consequences, injuries, or equipment damage. Mitigation of the risk should be accomplished within practical time and cost considerations.
10 - 19	2	Low	Attention is recommended for the optimal functioning of the recompression chamber facility. Risk mitigation steps already in place should at least be recorded.
< 10	1	Very low	The risk is acceptable. Note should be taken of the risk, but either it has already been suitably mitigated or its impact is of justifiably low significance.

Appendix B

Guidance on Chamber Air Specifications

Introduction

A great deal of confusion exists over the so-called minimum specifications for air - both breathing and medical grade. This is partly due to the fact that air is often stored in HP form, requiring additional corrosion considerations and therefore mandating uncomfortably dry air. However, the major debate centres on the safety aspects regarding the presence of HC and the definition of *oil-free* air.

National standards for air purity (based on acceptable impurity levels) do exist in most countries. However, these standards are not necessarily appropriate for oxygen-enriched environments found in hyperbaric chambers, necessitating a review of the international standards that are applicable.

The NFPA 99 standard has requirements for air that are both oxygen-compatible and medically safe. The resultant standard is classified as Medical Air (as defined by U.S. Pharmacopoeia or USP), with additional restrictions.

Although most national standards require stricter control on water vapour (H₂O), this is based on storage cylinder corrosion requirements, as opposed to patient considerations or oxygen-safety factors.

The following standard allows a greater amount of H₂O to be present (as do many of the international diving standards for surface-supplied air) for air up to 3.5 MPa (500 psi). It is important, to note there are additional requirements for air compressed to higher pressures, to avoid the risk of regulator freeze.

Specification

The required minimum specification air to be supplied to Class B chambers is:

Element	Requirement			
O ₂	20% to 22%			
Moisture	Compressed air for HP cylinder storage should meet the requirements of:			
	< 62 ppm _v (50 mg/m ³) or DT -46 °C (-51 °F) for cylinder pressures of between 4 - 20 MPa (580 - 2900 psi).			
	< 44 ppm _v (35 mg/m ³) or DT -49 °C (-56 °F) for cylinder pressures of between 20 - 30 MPa (2900 - 4350 psi).			
	< 33 ppm _v (25 mg/m ³) or DT -51 °C (-60 °F) measured at the compressor outlet.			
	Air supplied to the chamber downstream of all pressure reducing regulators need only meet the following requirements. The exception is a moisture limit of 62 ppm _v (-46 °C/-51 °F dew point) for air that passes through pneumatic controls.			
	Supply pressure MPa (psi)	Max H ₂ O content* mg/m ³ (ppm _v)	Supply pressure MPa (psi)	Max H ₂ O content* mg/m ³ (ppm _v)
0.5 (72.5)	290 (361)	2.5 (360)	65 (81)	
1.0 (145)	160 (199)	3.0 (435)	55 (68)	
1.5 (220)	110 (137)	4.0 (580)	50 (62)	
2.0 (290)	80 (99)	*Measured at 1 ATA & 20 °C (68 °F)		
CO ₂	CO ₂ to be less than 500 ppm _v (required where breathing pressures may exceed 1 ATA).			
CO	CO to be less than 5 ppm _v			

Element	Requirement
Oil	<p>As a liquid, oil is to be non-detectable.</p> <p>Liquid oil content is defined as a level of condensed HC, measured in mg/m³ at normal temperature and pressure. The lowest detectable level is 0.1 mg/m³.</p> <p>Where oil-lubricated compressors must be used, irrespective of the filtration system employed, the incoming chamber air supply should be continuously monitored downstream of the filters for oil content.</p> <p>Gaseous HCs, for example, methane (CH₄) are to be less than 25 ppm_v.</p>
Particulates	Concentration of particles to be < 0.5 mg/m ³ for particles greater than 5 µm in size.
Odor	None

Appendix C

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5. Schram PJ, Benedetti RP, and Earley MW, Electrical Installations in Hazardous Locations, 3rd edition, Jones & Bartlett Learning, 2009.
6. Workman WT, Hyperbaric Facility Safety: A Practical Guide, Best Publishing Company, 2000.

Additional Guidance Documents

1. American Society for Testing and Materials (ASTM) MNL36, Safe Use of Oxygen and Oxygen Systems: Handbook for Design, Operation, and Maintenance, 2nd edition, 2007.
2. American Society for Testing and Materials (ASTM) G88-13, Standard Guide for Designing Systems for Oxygen Service, 2013.
3. American Society for Testing and Materials (ASTM) G-93. Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen Enriched Environments, 1996.
4. American Society for Testing and Materials (ASTM) G94-05, Standard Guide for Evaluating Metals for Oxygen Service, 2014.
5. American Society for Testing and Materials (ASTM) G127-15, Standard Guide for the Selection of Cleaning Agents for Oxygen-Enriched Systems, 2015.
6. European Industrial Gases Association (EIGA), various free, downloadable publications that provide guidance on equipment and practices for oxygen and oxygen-enriched environments, as follows (see <https://www.eiga.eu/publications/catalogue-of-publications/>):
 - a) Doc. 04/18, Fire hazards of oxygen and oxygen-enriched atmospheres, 2009.
 - b) Doc. 10/17, Reciprocating compressors for oxygen service, 2017.
 - c) Doc. 42/16, Flexible connections in high pressure gas systems, 2016.
 - d) Doc. 138/15, PTFE used as a sealant for cylinder/valve connections, 2015.
 - e) Doc. 154/16, Safe location of oxygen and inert gas vents, 2016.
 - f) IGC Doc. 13/12, Oxygen pipeline and piping systems, 2012.
 - g) IGC Doc. 97/03: Valve outlet connections for gas cylinders, 2003.
 - h) Safety Info 15/08/E, Safety principles of high-pressure oxygen systems, 2008.
 - i) Safety Info 16/12/E, Fires in cylinder regulators in industrial oxygen in service, 2012.
7. International Organization for Standardization (ISO) 10083:2006(en), Oxygen concentrator supply systems for use with medical gas pipeline systems, 2006.
8. Joint industry project, Emergency Life Support Equipment for Commercial Diving Operations, January 2016 (see <http://www.dmac-diving.org/guidance/JIP-201602.pdf>).
9. National Fire Protection Association (NFPA) 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Suppression Systems, 2017.

Section 2

Clinical Multiplace Hyperbaric Facilities

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Clinical Multiplace Hyperbaric Facilities

Scope

This Risk Assessment Guide is intended to apply to hyperbaric treatment facilities that are technically and operationally equipped to provide HBO. It addresses the various types of hazards associated with these facilities and details specific measures that need to be taken to contain the identified risks.

The scope of this guide is focused on the technical, operational, and safety aspects of multiplace HBO facilities. Medical decisions related to the treatment of patients remain subject to professional medical judgment and the availability of therapeutic resources.

Where the equipment in a hyperbaric facility has been specifically designed for this application and is fully compliant with the provisions of the relevant codes and standards, there should be no distinct hazard to human life, and no alterations to such equipment are required. However, the safety factors relating to the environment in which such equipment is operated still need to be assessed.

Purpose

The primary purpose of this guide is to provide a means of assessing whether an existing facility complies with minimum safety requirements for the treatment of medical patients. It should enable the appointed safety representative to methodically and comprehensively assess the risks that a health care facility, HBO facility, operators and patients may be exposed to whilst being treated within a clinical hyperbaric facility and to remove, mitigate or minimise these risks.

In most instances, the Medical Director is legally responsible for the safety of the hyperbaric facility but may not be trained or competent in the appropriate safety issues. The guide is intended to provide the Medical Director with an objective means of ensuring that the hyperbaric facility, including additional or ancillary equipment, will be safe in accordance with reasonable occupational and technical principles.

In addition, it is also intended as a safety guide for the following purposes:

- to provide guidance in the acquisition of a new HBO facility; or
- to provide guidance for modifications or additions to an existing facility.

Basis

The basis for the compilation of this guide was a thorough analysis of the risks that are inherent to the following situations:

- the exposure of humans to hyperbaric pressures;
- the restrictive nature of hyperbaric chambers;
- the fire and explosion hazards associated with hyperbaric equipment;
- the multitude of associated mechanical and physiological hazards; and
- the hazards inherent in operating potentially dangerous machinery.

Each of these risks has been considered in the light of actual, quantifiable risks and of minimum measures required to mitigate, remove, or acceptably contain potentially hazardous situations.

Applicable Statutory Regulations and International Guidelines

The operation of pressure vessels for human occupancy, the operation of dangerous machinery, and general occupational health and safety provisions are commonly controlled by regional or national statutory or regulatory provisions. Neither this guide nor any other single document, code of practice, or set of operating instructions can supersede the requirement to comply with such provisions. All applicable statutes, regulations, standards, bylaws, and other regulatory instruments take legal precedence over the recommendations contained within this guide.

Many countries do not prescribe safety standards. This guide, originally commissioned by the Southern African Undersea and Hyperbaric Medical Association (SAUHMA), has been specifically compiled to facilitate safety assessments of hyperbaric treatment facilities that are located where safety standards are lacking – or as a supplement to applicable statutes and regulations.

This guide does not claim to comply either in part or in whole with any or all of these documents. Also, the listed documents typically apply to facilities that deliver a wide range of services and therapies, and only the issues and risks relevant to HBO treatment facilities have been considered here.

System Guidance Documents

- National Fire Protection Association (NFPA) *NFPA 99, Health Care Facilities*, 2018.
- Undersea and Hyperbaric Medical Society. *Guidelines for Clinical Multiplace Hyperbaric Facilities*, Kensington, MD, USA, 1994.

System Standards

- Australian/New Zealand Standard (AS/NZS) 2299.1.2007, Occupational Diving Standards – Standard
- American Society of Mechanical Engineers (ASME) *PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy*, 2016.
- American Society of Mechanical Engineers (ASME) *PVHO-2, Safety Standard for Pressure Vessels for Human Occupancy: In-Service Guidelines (guidelines for PVHO acrylic windows)*, 2016.
- European Standard EN 14931:2006, Pressure Vessels for Human Occupancy (PVHO). Multi-place pressure chambers for hyperbaric therapy. Performance, safety requirements and testing, 2006.
- European Standard EN 12021:2014, Respiratory equipment. Compressed gases for breathing apparatus, 2014 (including November 2014 corrections).
- European Standard EN 16081:2013, Hyperbaric chambers – Specific requirements for fire extinguishing systems – Performance, installation and testing (Austrian standard), 2013.

International Classification Society Rules

- American Bureau for Shipping (ABS): *Rules for Building and Classing Underwater Vehicles, Systems and Hyperbaric Facilities*, 2017.
- Lloyd's Register of Shipping (LR): *Rules and Regulations for the Construction and Classification of Submersibles and Diving Systems*, 2018.

Additional Guidance Documents

- American Society for Testing and Materials (ASTM) G-93-96, Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments, 1996.
- Australian Standards (AS) 4774.2-2002, Work in compressed air and hyperbaric facilities, Part 2: Hyperbaric oxygen facilities, 2002.
- Compressed Gas Association (CGA) G-7.1-2018, Commodity Specification for Air, 7th edition, 2018.
- Compressed Gas Association (CGA) G-4.1, Cleaning Equipment for Oxygen Service, 7th edition, 2018.
- Compressed Gas Association (CGA) P-45-2018, Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres, 2nd edition, 2018.
- European Industrial Gases Association (EIGA) 33/18, Cleaning of Equipment for Oxygen Service, 2018.
- National Fire Protection Association (NFPA) 70, National Electrical Code, 2017.
- Naval Sea Systems Command, US Navy Diving Manual, Revision 7, 2017.

Readers Note: Specific attention has been devoted to fire safety, potentially the greatest threat to and most life-threatening risk within a hyperbaric facility. Thus, as far as is practical, the NFPA Guidelines have been applied. It is of importance to note that the NFPA 99 Standard is internationally recognised to have the most effective and lasting safety record, and represents the most comprehensive fire prevention standard in existence.

Explanation of Terms

The following key terms are defined in the context of this guide.

Class A Chamber - An air-environment, multiple occupancy or multiplace chamber.

Class 1 Division 1 - Implies a location in which ignitable concentrations of flammable vapours can exist under normal operating conditions or can exist frequently due to leakage.

Class 1 Division 2 - Implies a location in which flammable vapours are present, but in which these substances are normally confined within closed systems, or where ignitable concentrations of these substances are prevented by ventilation.

Competent - The use of the term “competent” as applicable to a person or authority throughout the context of this document, should, in all cases, be defined as a person or authority who is competent to perform or certify an activity, by virtue of their training, knowledge and experience, which is specifically applicable to the design, manufacture, testing, inspection, installation, management and/or operation of hyperbaric facilities or equipment.

Grounded - Connected to earth, generally to the body of the chamber, in order to provide a low-impedance return path for leakage and fault currents.

Intrinsically safe - Apparatus comprising electrical circuits in which any spark or thermal effect is incapable of causing ignition of a flammable mixture or combustible material in air.

Medical Director - A registered and suitably qualified medical practitioner, responsible for all medical activities and for the direction, quality, safety and service provided by the facility. This person is usually appointed in terms of occupational health and safety legislation as the “user”; and therefore bears the overall responsibility for the facility under national legislation. This person, or a qualified designate, should be available throughout all treatments.

Oxygen-enriched - Any atmosphere, environment, or condition in which the concentration of oxygen exceeds 23.5% by volume.

Responsible - The use of the term ‘responsible’ as applicable to a person or authority throughout the context of this document, refers to a facility’s owner, manager, Medical Director or Safety Officer. In most countries, it is mandatory under occupational health and safety regulations to affect this appointment in writing.

Safety Officer - An appropriately qualified and competent person, delegated by the Medical Director and who is in charge of all equipment, operations, maintenance and safety-related matters, and authorised to control the access of equipment and supplies to the chamber within the facility. The term Safety Officer is synonymous with **Safety Director**, as used in some jurisdictions. This person should be involved in all aspects of planning, regulations and use of the facility.

Specialist - The term ‘specialist’ as used in this document should be assumed to include competent persons, professionally qualified experts (e.g., fire engineers or electrical or electronic engineers), and representatives of organizations recognized as specialists in a particular field.

Readers Note: A hyperbaric chamber environment is not classed as a Class 1 location due to oxygen-enriched concentrations. The possible introduction of flammable vapours (e.g., from alcohol swabs or medical dressings) into hyperbaric chambers, combined with the presence of sufficient combustible materials (including human skin) necessitates the specification of Class 1 requirements for the electrical systems, which potentially contain high-energy ignition sources.

Explanatory Notes

A risk is based on these three factors: 1) the probability that 2) an exposure to a hazard will result in 3) harmful consequences. The risk is higher where there is greater probability that an event will occur, greater frequency of exposure to a hazard, and/or greater severity of the consequences. Unless all three of these factors are present, no risk exists.

A *hazard*, by contrast, is a potentially harmful situation or agent. A *risk* results from exposure to a *hazard*.

The terms *hazard* and *risk* tend to be used interchangeably in many documents. In this document, however, *risk* refers to the probability of an adverse event, whereas *hazard* refers to the harmful situation itself.

The process of assessing risks associated with a multiplace hyperbaric oxygen treatment facility commences with a review of the impact of hazards associated with such facilities. The table below provides a description of each of the potential hazards and its associated risks.

Table 1: Nature of Hazards Applicable to Class A Multiplace Hyperbaric Chambers

Element	Description of Potential Hazards
<p>Fire and/or Explosion <i>Fire prevention within a Class A chamber is essential, as extinguishment inside the chamber where oxygen levels are elevated is difficult.</i></p>	
<p>General description</p>	<p>Fire requires the presence of (1) a combustible or flammable material, (2) an oxidising environment, and (3) a source of ignition, either heat or energy.</p> <p>Under hyperbaric conditions, the reactivity of the oxidising environment is greatly increased, due to the increase in the partial pressure of the oxygen. This applies to air as well as to oxygen.</p> <p>In air-pressurised chambers, leakage of oxygen into the chamber environment due to improper or ineffective breathing apparatus sealing interfaces will dramatically increase the oxygen partial pressure.</p> <p>The flammability of materials increases as the partial pressure of oxygen increases, to the point where normally non-combustible materials may become flammable or combustible. Partial pressure of oxygen increases as chamber internal pressure increases, irrespective of whether the oxygen percentage also increases or not.</p> <p>Where the oxygen concentration exceeds 23.5% or more (defined as oxygen enriched atmosphere) at elevated total pressure, flame propagation increases rapidly. All survivable fires in hyperbaric chambers have occurred where the oxygen percentage was below 23.5%.</p> <p>The heat of combustion rapidly increases the local environmental pressure, causing the internal pressure within a hyperbaric chamber to exceed intended or safe working pressures.</p> <p>The results of a chamber fire thus include the depletion of oxygen in a breathing environment, the production of toxic gases and products, the combustion of human tissue, and the over-pressurisation of the pressure vessel.</p> <p>Much of this discussion on fire and explosion is equally valid for non-hyperbaric oxygen enriched situations and thus applies to any situation where oxygen concentration increases within a confined space.</p>
<p>Sources of fuel</p>	<p>The discussion is limited to materials generally not considered as sources of fuel, or where the combustion behaviour is dramatically different to that expected under normal circumstances. These include:</p> <p>Certain types of flame-resistant fabrics, silicone rubber, polyvinyl chloride, asbestos containing paint, glass fibre, polyamides, epoxy compounds, certain asbestos blankets and lubricants are all examples of materials that generally either require a high temperature for ignition, or do not combust in air at atmospheric pressure. These materials all burn vigorously in an oxygen-enriched environment.</p> <p>Flammable anaesthetizing compounds.</p> <p>Human tissue, body hair, oils and fats that will burn readily in an oxygen-enriched environment.</p> <p>Loose cotton garments, employed throughout hospitals, that will ignite in 23% oxygen environments and will be totally destroyed in a 100% oxygen environment within 20 seconds.</p>

Element	Description of Potential Hazards
Sources of fuel (cont.)	<p>Combustible fabrics “absorb” oxygen as the tiny air spaces become saturated with oxygen during treatments. Once removed to atmospheric air, these fabrics will burn (if ignited) almost as rapidly as if still within an oxygen environment. This hazard remains until sufficient time has elapsed for the oxygen to diffuse out and be replaced by air.</p> <p>Oil-based or volatile cosmetics (facial creams, body oils, hair spray, etc.) all constitute a source of fuel.</p>
Sources of ignition	<p>The following list is not exhaustive but illustrates several known sources of ignition: defective electrical equipment, high-voltage monitoring or radiological equipment, heated surfaces in broken vacuum tubes or lamps (even lamps used for illuminating diagnostic equipment and monitoring), hot-wire cautery or high-frequency electro-cautery, open or arcing switches, overheated motors, brushed motors, bare defibrillator paddles and electrical thermostats.</p>
	<p>The more obvious sources include: lighted matches or tobacco, static sparks from improper personal attire (manufactured using synthetic materials), non-compliant electrical wiring and oil-contaminated materials that present a spontaneous heating hazard.</p>
	<p>In oxygen-enriched environments, the minimum energy for ignition reduces greatly in relation to ambient air environments.</p>

Element	Description of Potential Hazards
Mechanical Hazards	
Potential energy	<p>Even small volumes of compressed gas represent a large amount of potential energy. Should this energy be released suddenly, the effects on adjacent structures and personnel can be devastating. The release could be a result of failure of the vessel or the associated piping.</p>
Deviation from code or standard	<p>The above hazard may be created if the vessel is modified in a manner contrary to the original code or standard of design and construction.</p>
Access	<p>Any restriction on escape or impedance to rescue and firefighting efforts posed by the chamber create a hazard in case of an emergency.</p>
Patient	<p>In the event of a fire within the structure housing the chamber, a hazard exists to the patient inside the chamber. Inability to escape and loss of the chamber operator would pose a serious threat to the patient’s life.</p>
Visibility	<p>Reduction or restriction of vision of chamber operators reduces their effectiveness as safety monitors.</p>
Sealed or semi-sealed containers	<p>Containers that may present hazards due to collapse or rupture during changes in pressures include ampoules, stoppered bottles, or capped bottles (e.g. multi-dose vials and glass intravenous infusion sets), air-filled cuffs used for breathing masks or positioning patients.</p>
	<p>Any air-filled containers taken into a chamber that are not adequately vented will either: collapse under pressure (possibly resulting in adiabatic heating of the contents and thus imposing a fire or explosion risk); or explode on resurfacing if the gas trapped within the container cannot escape during the ascent.</p>
Other hazards	<p>Other mechanical hazards relate to the malfunction, disruption or inoperativeness of many standard items when placed in service under hyperbaric conditions. These also include the implosion of lamps and vacuum tubes (e.g. cathode ray tubes in medical monitors), overloading of fans due to a higher gas density, inaccurate operation of flow meters, pressure gauges and regulators.</p>

Element	Description of Potential Hazards
Physiological Hazards <i>As stated under the scope of this assessment, medical considerations and complications are specifically excluded. The only hazards thus included under this section are those arising as a result of mechanical, electrical or other safety malfunctions.</i>	
General hazards	These include electric shock and the fouling of the atmosphere with carbon dioxide (CO ₂), carbon monoxide (CO), pyrolysis products from overheated materials, or toxic products generated during the combustion of materials (e.g. cyanide and chlorine).
CO ₂	Should the ventilation or air exchange system malfunction or be inadequate, CO ₂ levels could rise to toxic levels (due to the increased atmospheric pressure).
Rapid depressurisation	Rapid release of chamber pressure can lead to shock waves, noise and loss of visibility due to condensation of moisture in the chamber atmosphere. This may result where over-pressurization occurs, and the relief valve is activated.
Noise	During compression and subsequent ventilation, noise levels for the patient can be uncomfortably high.

Not all risks carry the same consequences or need for urgent attention. It is thus deemed prudent to use a risk level (RL) rating scale, as outlined in Table 2 below (and detailed in Appendix A):

Table 2: Risk Rating and Associated Requirements

RL	Risk Rating	Requirements
5	Very high	Attention and risk mitigation are critical and must be given highest priority. A potentially dangerous situation may exist, with the possibility of very serious or catastrophic consequences in the event of an adverse incident. Treatment activity should stop immediately and should not recommence until effective mitigation is in place.
4	High	Attention and risk mitigation are required and must be given high priority. A serious situation may exist that could endanger people or equipment or that could seriously disrupt or jeopardize the business. Solutions or actions that may mitigate the risk should be considered, at the discretion of the Safety Officer (see below for a definition of this term as used in this guide), and they should be recorded in writing.
3	Medium	Attention to the risk is required. Eventual exposure to this risk could likely result in an incident. Outcomes could include business disruption, financial or liability consequences, injuries, or equipment damage. Mitigation of the risk should be accomplished within practical time and cost considerations.
2	Low	Attention to the risk is recommended for the optimal functioning of the facility. Risk mitigation steps already in place should be recorded in writing.
1	Very low	The risk is acceptable. Note should be taken of the risk, but either it has already been suitably mitigated or its impact is of justifiably low significance.

However, risk levels may vary on a case by case basis, as a result of the following factors: 1) the type or nature of the facility; 2) the degree of qualified discretion allowed by national or local authorities; and 3) a determination by the Safety Officer of whether a risk is relevant.

During self-assessments by a facility, all risk levels 3, 4 and 5, as detailed in Table 2 above, should be addressed prior to regarding the facility as safe enough for regular operations.

The Risk Assessment Process

The following explanation illustrates one suggested method for applying this Guide in order to determine the degree of safety of a multiplace treatment facility. The process commences with an assessment of the applicable risks that affect a facility. The risks need to be identified as applicable, or as deemed appropriate by the Safety Officer. Guidance as to the importance of each classified risk is offered in the form of a risk level. The actual risk level may differ or be otherwise indicated by the Safety Officer as may be applicable in each case.

This is followed by a detailed physical evaluation of the facility in terms of its conformance to the relevant minimum requirements. It would be deemed appropriate for the facility's Safety Officer to describe in detail how each of the applicable minimum requirements has been complied with.

Where compliance with national or local regulations is stated, but where no such regulations exist, or are considered inappropriate for the facility, the Safety Officer should comply with the appropriate guideline detailed under the applicable minimum requirements has been complied with above.

Where *specialist* advice suggests that exceptions to the minimum requirements are acceptable, these should be expressed in writing, together with all the motivating considerations, and presented to the owner or user for acceptance and endorsement.

In preparation for safety assessments or external review, this process should be undertaken in writing, specifically as it relates to the assessment of actual or likely risks and the compliance or non-compliance with the minimum applicable requirements.

This process should also be followed when any change in the status of equipment is anticipated, prior to equipment modification or prior to the acquisition of new equipment. An HBO treatment facility is an integrated unit, where even small changes to certain items may impact greatly on the overall operational safety.

Element: Chamber room lighting (typically a Risk Level 3)

Step 1: Identification of actual risk:

Ultraviolet light results in deterioration of chamber acrylic windows. Direct sunlight, mercury vapour discharge and certain types of fluorescent lighting are known sources of detrimental UV radiation.

Step 2: Application of minimum requirement(s) to address, remove or mitigate the risk:

Monoplace chamber windows should not be exposed to direct sunlight. Where fluorescent lighting is preferred, this lighting should be selected on the basis of an appropriate UV spectrum range (with only UV radiation with a wavelength above 320 nm being released at more than 30 cm (1 ft) from the lamp).

Comments:

All forms of fluorescent lighting, including the compact fluorescent lamp (CFL), produce UV radiation.

UV radiation is classified in 3 main ranges, based on wavelength in nanometers (nm):

UVA: ±320 - 400 nm: the least harmful, and almost negligible at distances of 30 cm (1 ft) and further.

UVB: ±290 - 320 nm: in sufficient quantities, causes sunburn and cancer. It also degrades acrylic windows.

UVC: ±10 – 290 nm: the most hazardous range to humans; typical used in germicidal applications.

The glass tubes used in incandescent, fluorescent and CFL lamps absorb almost all UV radiation. At distances greater than 30 cm (1ft), the amount of harmful UV light is negligible.

Metal vapour lamps, specifically metal halide and mercury lamps can produce sufficient UV light in the UVB range to degrade acrylic materials.

Where the minimum requirement cannot be met, the Safety Officer may exercise discretion by, for example, installing UV filters (covers, screens and films) between the source of UV radiation and the chamber acrylic window. In all cases, where such discretion is employed, this must be expressed in writing, endorsed by the owner or user, and preferably filed together with the completed compliance document.

Guidelines: Applicable Risks & Minimum Mitigation Requirements

1. Construction and Equipment				
Ref.	Element	Risks	RL	Minimum Requirements

1.1 Housing of Hyperbaric Facilities

1.1.1	Standard for Health Care Facilities	The risks associated with this hazard include fire safety, building safety, mechanical equipment safety, personnel safety, and operational safety.	3 3	<p>a) National statutes, regulations, or standards and local bylaws or ordinances should be followed, especially as to fire safety and building and general facility matters.</p> <p>b) Chapter 14 of NFPA 99 (the National Fire Protection Association code pertaining to health care facilities) addresses all pertinent risks on a thoroughly integrated and comprehensive basis; it is specifically relevant to hyperbaric facilities and should be used for additional guidance.</p>
1.1.2	Size of room housing the HBO chamber	<p>Inadequate room size presents accessibility risks during both routine and emergency situations, thereby compromising facility safety, patient and staff care and health.</p> <p>Multiplace chambers are frequently installed with piping and cabling under the flooring, inside the ceiling, and behind panelling used to conceal supporting attachments and assist in reducing patient anxiety.</p> <p>Concealed and inaccessible spaces are difficult to keep clean and restrict routine maintenance such as pipe leak testing.</p> <p>The build-up of dust and other flammable materials, together with pooling of oxygen from pipe leaks, presents an elevated risk of fire.</p>	3	<p>Sufficient space should be allocated, prior to installation and/modifications, to ensure realistic access to the control panel(s), emergency equipment and shut-off valves, piping, cabling, valves, windows, hatches, safe patient and staff ingress and egress, patient extraction during an emergency, and equipment associated with both the room as well as the chamber.</p> <p>Consideration should be given for access to hidden spaces for dealing with possible fires, performing regular housekeeping and routine maintenance.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.3	Space for emergency procedures	Inadequate space to handle cardiac arrests, seizures or other patient medical complications could severely compromise the patient's health. Resuscitation equipment such as defibrillators may present an additional hazard where high oxygen concentrations are present.	3	All installations should be provided with adequate spaces for such emergencies. Where adequate resuscitation equipment is available in nearby locations in the hospital, these need not be provided within the HBO facility.
1.1.4	Patient support considerations	Cluttered and inappropriate accommodation of patients could lead to compromised care and inability to concentrate on other safety-related issues.	3	It is recommended that the facility have sufficient space allocated for patient examination and evaluation, wound care, medical supplies, patient lockers, ablution facilities and a waiting area.
1.1.5	Exclusive use of rooms housing the HBO facility	Use of other, non-related hazardous equipment in a room housing a hyperbaric chamber could compromise the safety of the entire HBO facility.	3	Rooms housing HBO facilities should be for the exclusive use of the facility. Ancillary HBO equipment may be housed within these rooms.
1.1.6	Supporting foundations for the hyperbaric chamber.	Inadequate supporting foundations could cause failure of the building support structures, especially during on-site hydrostatic testing.	4	All supporting foundations should be strong enough to support the chamber during all intended operations, preferably including hydrostatic pressure testing. This requirement may be reduced where the chamber could be removed for any future welding repairs or modification work, or where pneumatic pressure testing may be allowed under applicable statutory testing requirements. Ground floor location of the chamber is the preferred option.
1.1.7	Flooring	Non-conductive flooring may result in the build-up of a static charge on operator(s). The risk of this causing a fire outside the chamber is considered to be low.	2	Conductive flooring is not mandatory for any chamber treatment facilities as the discharge to ground will be an inconvenience rather than a safety issue. Some electronic devices may be damaged when part of the path to ground.
1.1.8	Room temperature	Humidity and temperature control affect static electricity, as well as patient comfort and operator attentiveness.	3	Rooms housing chambers should be provided with air conditioning for compliant temperature and humidity control.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.9	External fire protection of facility rooms	A fire occurring outside of the HBO facility and endangering patients, operators and other staff presents an additional risk in that the patients cannot immediately be extracted from the chamber.	3	<p>HBO facility rooms should be of fire-resistant construction, e.g., a 2-hour fire-resistive rating, or should be offered sufficient protection from an outside fire to allow the chamber to be surfaced (depressurised) and patients and staff evacuated safely.</p> <p>All interconnecting doors should be rated as at least 1½ hour fire-doors.</p> <p><i>Note: A possible exclusion may apply to mobile or temporary facilities.</i></p> <p><i>Mobile facilities are those where the chamber has specifically been designed and certified as a mobile or transportable portable unit.</i></p> <p><i>Temporary facilities are defined as those where the facility will be operated in a specified location for a maximum period of 3 months.</i></p> <p><i>However, and in all cases, exclusions should be subject to a site risk assessment, approval by the local fire protection authorities and should comply with whatever additional protective and safety measures have been deemed applicable by such authorities.</i></p>
1.1.10	Fire protection of rooms housing the chamber & ancillary equipment	<p>A fire in the chamber or equipment room may endanger:</p> <ul style="list-style-type: none"> a) the facility staff and patients, both inside and outside the chamber; b) the operators, preventing them from remaining at their posts during the required emergency termination and evacuation process; c) the chamber and ancillary equipment; d) the continued operation of ancillary equipment, preventing safe termination of the treatment; e) the remainder of the health care facility. 	3	<p>An automatic, wet sprinkler system designed and installed in accordance with local and/or national regulations pertaining to health care facilities should be fitted in the chamber room, treatment areas, as well as in the ancillary equipment rooms.</p> <p>Mobile, temporary facilities and facilities housing chambers that are not fixed to the foundations are excluded from these requirements.</p> <p>Alternatively, where this is not deemed to be a requirement by local regulations, at least two portable fire extinguishers should be strategically located within the room.</p> <p><i>Note: Minimum national regulations take precedence although it remains a strong recommendation that a sprinkler system should be installed.</i></p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.11	Design & selection of room sprinkler heads	<p>The sprinkler system must ensure sufficient time to bring the chamber back to atmospheric pressure and to evacuate the patients.</p> <p>The system must also prevent spreading of the fire to other parts of the health care facility.</p>	3	<p>National regulations that apply to both the number and type of sprinkler heads required for installation in health care facilities should be complied with.</p> <p>In addition, sprinkler heads should be equipped with low-rated fusible elements, offer a degree of direct protection to the chamber operator(s), and protect the chamber and ancillary equipment as much as possible.</p> <p>This clearly requires specialist advice.</p>
1.1.12	Facility fire protection equipment	<p>Failure of any fire-suppression system control equipment jeopardizes the ability of the system to effectively extinguish a fire.</p>	4	<p>Quarterly visual inspections of fire-suppression system functioning components should be conducted.</p> <p><i>Note: While fire alarm and deluge systems usually form part of a centralised department, or are performed by an external company, a hyperbaric facility has more restrictive evacuation options and careful attention to inspections, documentation and an even more frequent inspection schedule may be needed, based on the age and condition of the system.</i></p>
1.1.13	“No Smoking” signs	<p>Any source of open flame presents a hazard in a location where the possibilities of high oxygen concentrations exist.</p>	3	<p>Signs prohibiting smoking should be clearly displayed both within and outside the HBO facility and a strict policy of no smoking should be enforced within the unit.</p>
1.1.14	Lighting (UV)	<p>Ultraviolet light results in deterioration of the chamber acrylic windows.</p> <p>Direct sunlight, mercury vapour discharge and certain types of fluorescent lighting are known sources of detrimental UV radiation.</p>	3	<p>Chambers should not be exposed to direct sunlight.</p> <p>Where fluorescent lighting is preferred, this lighting should be selected on the basis of an appropriate UV spectrum range (with wavelength above 320 nm).</p>
1.1.15	Lighting	<p>Flickering lighting may affect patients with higher flicker fusion thresholds, inducing eyestrain, headaches, fatigue and even seizures.</p>	3	<p>Controlled incandescent lights or dimmable fluorescent lighting fitted with electronic ballast (20 - 60 kHz frequency range) are suitable for use.</p> <p>All fluorescent lamps should be maintained and replaced appropriately.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.1.16	Telephonic communication	<p>In the event of an emergency, the operator may not leave the HBO facility.</p> <p>Without an effective communication link with outside services, the operator would have to leave the control panel, losing contact and sight of the patients.</p>	4	The HBO facility should be linked to the clinical facility by means of a telephone extension, as well as an intercommunications unit, as well as a manual alarm activation device.
1.1.17	Cleanliness	Apart from health risks, greases, oils and dirt present additional fire hazards in areas where high oxygen concentrations may be present.	3	The HBO facility should be cleaned regularly to the satisfaction of the Medical Director.
1.1.18	Floor wax/polish	Commercial floor polishes and waxes often contain hydrocarbons (HCs) and also impede conductivity with the floor.	3	<p>Floors should not be coated with HC-based products that may be entrained into the chamber.</p> <p>Coatings should also not affect the conductivity of flooring.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.2 Design & Construction of a Multiplace Hyperbaric Chamber

1.2.1	Design of Hyperbaric Chambers and safety standards	<p>The utmost care must be taken in the initial design of a chamber, because once a unit is constructed and installed, structural changes to the pressure vessel are exceedingly difficult to carry out in complete safety.</p> <p>The use of inadequate, inappropriate, and/or unsuitable safety standards can compromise operator, attendant, patient, and/or facility safety; can compromise the safety of the entire health-care facility; and can result in noncompliance with relevant statutes and regulations.</p> <p>Pressure vessels are classified as hazardous equipment.</p>	<p>3</p> <p>2</p> <p>3</p> <p>4</p> <p>3</p> <p>4</p>	<p>a) During the design of a chamber, all aspects of the chamber’s operation relevant to its intended use should be considered – e.g., internal size, layout, number of occupants, storage shelves and bracketry, and maximum working pressure.</p> <p>b) It is recommended that multiplace chambers be rated to a working pressure of at least 3 ATA (29 psig)</p> <p>c) Chambers should be designed to meet the requirements of any of the internationally accepted and applicable safety standards, as well as any relevant national statutes or regulations.</p> <p>d) Care should be taken to ensure that the selected standards are applicable to pressure vessels for human occupancy (especially with regard to viewport design).</p> <p>e) The ASME PVHO-1 (American Society of Mechanical Engineers’ Pressure Vessels for Human Occupation) standard, which dovetails with NFPA regulations, is the preferred standard.</p> <p>f) In addition, an internationally accepted life-support standard should be used to determine requirements for chamber equipment, ancillary equipment, levels of redundancy, safety system equipment, and maintenance, all as applicable to the intended use of the chamber.</p> <p>Examples of such standards include AS/NZS 2299, ABS, and LR.</p>
1.2.2	Approved treatment chambers	<p>The use of pressurized equipment and the exposure of materials to high oxygen concentrations and pressures are associated with a range of mechanical, fire and physiological hazards.</p> <p>Insurance risks and statutory compliance risks are also relevant.</p>	4	<p>The requirements of the appropriate safety standard, international guidelines for vessels for human occupancy, legal statutes and insurance companies should be addressed.</p> <p>Compliance should be demonstrated through certification by an approved inspection authority.</p> <p>A copy of the original certification document should be retained at the facility.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.3	Chamber flooring	Structurally unsound flooring may distort or shift, causing patients and/or medical personnel to trip or fall.	3	Flooring should be capable of supporting all equipment, personnel, and patients consistent with the intended use of the chamber.
1.2.4	Flooring materials	Certain flooring materials present risks of fire or falls.	4 4	a) Flooring should be non-combustible. b) Non-slip surfaces should be employed.
1.2.5	Access to bilges	Restricted access to a chamber's bilge area can hinder adequate cleaning of the area, resulting in a build-up of dirt and thus an increased fire and health risk.	3	If deck plates are fitted in place, adequate access to the entire bilge area should be provided to make effective cleaning and disinfecting of the area possible.
1.2.6	Securing of chamber flooring	Improperly secured flooring can be unstable, and electrically unbonded flooring can cause a break in electrical grounding.	3	Any flooring should be securely installed so as to prevent its movement and so as to ensure integrity of electrical conductivity. <i>Note: whatever method is used to secure the flooring should not restrict its removal for cleaning purposes.</i>
1.2.7	Chamber paint colour	Certain colors may elevate patients' anxiety and dampen internal light levels.	1	Care should be exercised in selecting paint colors for a hyperbaric chamber. Colors that have a calming effect and that enhance internal light levels are preferred.
1.2.8	Internal surface treatment or finish of chamber	Finishes that are chemically unstable, flammable, or otherwise unsuitable in a pressurized environment present both health and fire risks.	3	The interior of a chamber should either be untreated (e.g., if it is made of stainless steel) or be treated with a nontoxic, corrosion-inhibiting, low-flammability paint that is suitable for human occupancy and hyperbaric pressure applications.
1.2.9	Paint fumes	Initial off-gassing of curing painted surfaces can present a health hazard.	4	No chamber should be used within the first 72 hours after application of an internal surface treatment, unless otherwise specified in the relevant material safety data information issued by the paint manufacturer.
1.2.10	Sound deadening materials	Certain sound deadening materials present a fire hazard.	3	If sound-deadening materials are used within a chamber, such materials should be flame-resistant.
1.2.11	Doors	Door design may restrict entry into and exit from the chamber, especially during an emergency evacuation. Non-ergonomic designs and configurations may also lead to physical injuries, especially to staff.	3	Suitably-sized rectangular doors should be considered for the regular access points to the chamber. Where round doors are to be used, they should be sized and positioned so as to avoid restriction and physical injuries during entry into and exit from the chamber.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.12	Sufficient number of viewing ports & access ports for equipment	Inadequate allowance for visibility and access during the initial design and manufacture of a chamber may result in impaired ability to observe patients and/or may compromise the safe installation of monitoring and treatment equipment.	3 3	a) The initial design of a chamber should include a sufficient number of viewports and equipment access ports for piping, equipment, and monitoring leads. b) A suitable guide is to allow for at least 50% excess capacity of access ports or penetrations.
1.2.13	Viewport design	The design and maintenance of viewports are critical to safety and yet fall outside the scope of many international design and construction codes.	3 3	a) Viewports should be designed to meet the requirements of a safety standard that makes specific provision for nonmetallic, pressure-bearing structures. b) The service life requirements defined by a relevant safety standard should be followed. ASME PVHO-2 allows for a service extension based on a visual inspection by a competent person for use in a protected service environment.
1.2.14	Protection and care of viewports	Acrylic is easily scratched and/or damaged by certain forms of radiation, impact and/or inappropriate cleaning solutions. Certain cleaning fluids and UVB or UVC radiation may cause viewport deterioration. This may result in obscured vision, or damaged that reduces life span.	4 3 3	a) Outer protective shields may be considered to limit mechanical damage to the inner, pressure bearing window. b) Acrylic windows should not be exposed to direct sunlight or any other source of UVB or UVC radiation, or to any direct source of heat. c) Care should be exercised to ensure that correct cleaning solutions and procedures are enforced. The ASME PVHO-2 standard provides guidance on the care and use of acrylic viewports.
1.2.15	Weatherproofing of electrical access ports	If access ports and electrical penetrators have not been adequately weatherproofed, there may be a risk of electrical shock, short-circuiting or equipment damage during activation of an internal or external deluge system and/or during cleaning.	4	All electrical circuits should be housed in weatherproofed enclosures capable of withstanding a deluge from the fire protection system, the application of cleaning solutions, and/or any precipitation to which the chamber might be exposed.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.16	Door seals	Any damage to a door seal may result in chamber gas escaping under pressure, introducing a high oxygen concentration hazard into the surrounding area.	2	<p>Chamber door (O-ring or lipseals) seals should be easily repairable or capable of operating safely with minor damage.</p> <p>Operators should be trained to identify leaks at door seals and to inspect the seal integrity before and after treatments.</p> <p>Spare seals should be maintained in the facility.</p>
1.2.17	Seats, bunks or other fixtures	Fixtures and furnishings installed in a chamber may introduce into the environment flammable materials, mechanical hazards, and/or a source of electrostatic charges or discharges.	3	<p>Seats, bunks, and other fixtures should, whenever possible, be fabricated using nonsparking and non-combustible materials, be free of sharp edges and corners, and be designed for ease of installation and removal.</p>
1.2.18	Pressure-relief provisions	<p>Overpressurization of a chamber can result in a risk of mechanical damage or fire.</p> <p>Malfunctioning relief valves can compromise the safety of a chamber's patients.</p> <p>An excessively high set pressure may place the patient in danger from oxygen toxicity, nitrogen loading and rapid depressurization when the safety valve opens.</p> <p>Inadequate venting capacity of relief valves is a hazard that can lead to overpressurization.</p>	<p>5</p> <p>3</p> <p>5</p> <p>4</p> <p>4</p> <p>3</p> <p>4</p> <p>4</p>	<p>a) Chambers should be fitted with an over-pressure safety valve, designed and tested under regular inspection authority survey, to prevent the chamber pressure from exceeding the vessel design pressure.</p> <p>b) Consideration should be given to specifying a set pressure of no more than 15% above the maximum operational working (treatment) pressure.</p> <p>c) Safety valves should be designed to be fully open at no more than 3% above set pressure.</p> <p>d) The reseal pressure limit should be no lower than 7% below the set pressure, and this function should be tested regularly.</p> <p>e) Relief valves should be fitted with external isolating valves to allow for shutting off in the event of malfunctioning.</p> <p>f) Valve handles should be wired in the open position using breakable safety wire.</p> <p>g) Internal ports should not be blocked or obstructed in any way other than with a suitable anti-suction device.</p> <p>h) Safety relief valves should be sized such that no situation can exist whereby gas can be introduced faster than can be discharged.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.2.19	Chamber pressure (life-support) gauges	<p>Not all gauges are of suitable repeatability and accuracy for life-support applications.</p> <p>This could detrimentally affect the quality of treatments as well as the safety of patients.</p> <p>If gauges are incorrectly installed, controlled, and/or maintained, they may not function accurately or effectively.</p>	<p>4</p> <p>4</p> <p>4</p> <p>4</p> <p>4</p> <p>4</p> <p>3</p> <p>3</p>	<p>a) All chamber compartments should be fitted with an independent pressure gauge that can be read by an external operator.</p> <p>This is usually achieved by mounting the gauge on the control panel.</p> <p>b) Treatment locks should be fitted with internal caisson pressure gauges, or at least a suitable means of informing the occupants of the lock pressure.</p> <p>c) All gauges should be accurate and repeatable, should have scales appropriate for the expected pressure range, should be of a size suitable for easy readability (i.e., no smaller than 150 mm [6"] in diameter), and should be precise to a degree medically appropriate for measuring treatment pressures.</p> <p>Clinical hyperbaric oxygen treatment chambers are not usually used for deep treatments, which require accuracy during decompression.</p> <p>An accuracy of $\pm 0.5\%$ of the gauge's full scale, or better, is sufficient for chambers with treatment pressures under 3 ATA.</p> <p>Gauges used with pressures above this level should comply with the industry standard of $\pm 0.25\%$ of the full scale.</p> <p>As chamber pressure may vary between zero and full scale, a life-support gauge requires accuracy over the full range.</p> <p>d) Pressure gauge lines should not supply any other devices.</p> <p>e) Internal ports for gauge lines should be protected with a shield to prevent inadvertent blockage.</p> <p>f) All systems should be correctly cleaned prior to use, and regularly checked for leaks.</p> <p>g) Gauges should be tested over the full treatment range at least once a year to ensure accuracy.</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.3 Illumination

1.3.1	Location and design of lighting	<p>Lighting fixtures not designed for hyperbaric applications present a serious risk of explosion, implosion, and/or fire.</p> <p>There are also risks if the maintenance and inspection requirements for such fixtures are not followed.</p>	3	<p>The preferred location for mounting lights is on the outside of the chamber.</p> <p>However, interior use of lighting fixtures may be considered if the fixtures are designed to be pressure-proof (or pressure-compensatory and explosion-proof) and are certified by a competent design authority as suitable for use inside the chamber.</p>
1.3.2	Temperature of external lighting fixtures	<p>If lights are used in conjunction with viewports, excessive surface temperatures will compromise the integrity of the viewport lens material.</p>	4	<p>Lighting fixtures should be designed in accordance with the requirements of a suitable standard containing such provisions.</p> <p>Viewport temperature ratings should be considered during the design of such fixtures.</p>
1.3.3	Sealing materials for internal lights	<p>The dramatic pressure increases induced by the elevated surface temperature of luminaries may lead to premature failure of seals.</p> <p>This constitutes both fire and structural failure hazards.</p>	3	<p>Gasket and O-ring materials should be fire resistant, correctly temperature rated and should be designed and selected so as to accommodate movement due to thermal expansion.</p> <p>Fully captured or confined sealing enclosures should be used.</p>
1.3.4	Internally installed lights, including portable medical examination lights	<p>Electrical resistance lights are a source of heat, and if they are not suitably protected when used inside a chamber, there is a risk that they may provide sufficient energy for ignition.</p>	4	<p>Internal lighting fixtures in a chamber should meet the following requirements:</p> <ul style="list-style-type: none"> <li style="margin-bottom: 10px;">4 a) They should have an external operating surface temperature of less than 85°C (185°F); <li style="margin-bottom: 10px;">4 b) They should be rated for a pressure of at least 1½ times the chamber's maximum working pressure; <li style="margin-bottom: 10px;">3 c) They should be located away from areas where they may be physically damaged; and <li style="margin-bottom: 10px;">3 d) They should be designed for such applications and that fact should be certified by a competent design authority. <p>2 It is recommended that high-intensity local task lighting be provided using through-hull fiber-optic devices.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.3.5	Portable medical examinations lights	Portable lighting fixtures carry an additional risk that they may shatter or explode if they're dropped or accidentally damaged.	4 4	All externally powered portable lighting units should be of a self-contained, vented, and shatterproof design. The design should be in accordance with a recognized and applicable standard and certified as such.
1.3.6	Emergency lighting	An illumination failure in a chamber without adequate backup lighting can lead to risks for both patients and medical personnel. In addition, any emergency responders will be hampered in their ability to act, leading to additional risks.	3 3 3	a) Chambers should be fitted with sufficient lighting fixtures so as to provide suitable redundancy in the event of single failures. b) If a chamber has sufficient viewports, external room lighting may be sufficient to provide backup illumination. c) In addition, lighting power circuits should be connected to the chamber or health care facility's emergency power supply

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.4 Gas Supply Systems, Ventilation and Chamber Air Conditioning

Chamber Air Supply System Requirements				
1.4.1	Air pressurization system	<p>Insufficient air capacity for nonroutine or emergency treatments can compromise patient care during inadvertent power breaks that affect the compressor.</p> <p>Excessive moisture can affect the ability of filtration systems to work effectively.</p> <p>Condensed moisture can also influence control valves and result in accelerated corrosion in storage vessels.</p> <p>In addition, environmental particulates above a certain size can result in damage to the compressor's gas flow path</p>	<p>5</p> <p>3</p> <p>3</p> <p>3</p>	<p>a) Air compressors and storage vessels should be designed with sufficient capacity to complete a maximum-duration medical treatment, including pressurization, and to supply the maximum, continuous ventilation demand.</p> <p>b) Compressed air systems should be fitted with after-coolers to ensure that excess condensate is removed prior to storage.</p> <p>c) Compressors should be fitted with inlet filters capable of removing airborne particles larger than 10 µm in size.</p> <p>d) It is recommended that automatic drains be fitted to all filter housings.</p>
1.4.2	Sources of air for a chamber	<p>Toxic, flammable, or fouled air can be introduced into a chamber's air source by means that may be beyond the control of the facility's owner or manager.</p>	<p>5</p> <p>3</p>	<p>a) Compressor intakes should be located so that toxic, flammable, or fouled air cannot be introduced into a chamber's system.</p> <p>Typical sources of fouling include vehicular activity, internal combustion engines, other mechanical equipment, and building exhaust outlets.</p> <p>b) Warning signs should be posted at the locations of all compressor intakes.</p>
1.4.3	Handling of air for a chamber	<p>Unsuitable or malfunctioning air-handling equipment can contaminate the air supply to a chamber.</p> <p>Contamination with oil or other hydrocarbons (HCs) presents a particular hazard in oxygen-enriched environments.</p>	<p>4</p>	<p>The air supplied to a chamber should be monitored as detailed in section 1.7.7).</p> <p>Efforts should be made to ensure that all known causes of contamination are eliminated by following correct maintenance procedures and by conducting regular inspections of compressor seals, air purification devices, and compressor intakes and filters.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.4	Compressor air intake	<p>Inappropriately located and/or inadequately sized air-intake piping can lead to excessive air intake resistance or a starving of the compressor.</p> <p>This may result in reduced air output and pressure, overheating, excessive oil consumption, and damage to the compressor.</p>	3	<p>a) The introduction of any form of resistance to the flow of air, including remote location of a modified inlet filtration system without instruction or approval from the compressor manufacturer, should be avoided.</p> <p>As a general rule these criteria should be followed:</p> <ul style="list-style-type: none"> • The internal diameter of an intake hose should be increased by at least 6.35 mm (¼") for each 3 meters (10 feet) of extension, applied to the complete length of the hose; • If 90-degree bends or other similar flow restrictions need to be used, the internal diameter of the complete intake hose should be increased by 6.35 mm (¼") for each bend, and no more than four bends are recommended; • Provision should be made at the connection to the existing compressor intake to drain any condensate that might accumulate in the hose and run into the compressor intake; • The inlet to the extension hose should be covered with mesh to prevent insects or debris from being drawn in, and the opening should also face downward to avoid any direct rain from entering the hose; • The use of any form of filter at the inlet to the extended hose should be avoided; • The manufacturer's requirements and recommendations, if available, always take precedence. <p>b) Any extension of an intake hose should account for the added flow resistance.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.5	Use of oil-lubricated compressors	<p>If a chamber is served by an oil-lubricated compressor, a failure of the air-treatment package, inadequate maintenance procedures, or a failure of the compressor system could introduce oil and/or other HCs into the chamber's air supply.</p> <p>This presents a major risk of fire, especially in an oxygen-enriched environment.</p>	<p>3</p> <p>3</p> <p>3</p>	<p>a) If a chamber is served by an oil-lubricated compressor, it should be fitted with an air-treatment package specifically designed to produce breathing air (see 1.7.7).</p> <p>b) Air-treatment packages on oil-lubricated compressors should be fitted with automatic safeguards to ensure either that contamination cannot occur or, if it does, that the air-supply system will shut down before the contamination can reach the chamber.</p> <p>c) Oil-lubricated compressors and associated air-treatment packages should be diligently monitored and maintained.</p>
1.4.6	Redundant air-supply capabilities	<p>A failure of a chamber's air-supply system, especially during a life-threatening emergency treatment, can seriously compromise the patient's condition and the efficacy of the treatment.</p>	<p>3</p> <p>3</p> <p>3</p>	<p>a) Air-supply facilities should consist of two or more individual systems, each with sufficient capacity to maintain the required flow rates on a continuous basis.</p> <p>This requirement may be met by using one large compressor, typically with a low-pressure rating, and one standby compressor, typically with a high pressure (HP) rating, which can be used to fill an adequately sized HP storage tank.</p> <p>Other acceptable options include two low-pressure compressors; two suitably sized HP compressors; or a large supply of stored air.</p> <p>b) At least one system should meet the pressurization and ventilation requirements of the full duration of any intended treatments.</p> <p>The standby system should meet the requirements of the full duration of the longest table used for life-threatening treatments (for example, the extended USN TT 6A [U.S. Navy Treatment Table 6A]).</p> <p>c) Each compressor should be supplied from a separate electric branch circuit.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.7	Gas quality	<p>Unknown or non-certified gases may introduce flammable or combustible compounds into the chamber.</p> <p>Calcite crystals are known by-products of water-based lubricants used in certain oil-free (Teflon ring) gas compressors.</p> <p>Environmental particulates above a certain size can result in damage to the compressor's gas flow path.</p>	4	<p>HC and 5 µm particulate in-line filters should be used to remove contamination - preferably 1 µm filters where non-certified or suspect gas supplies are provided, from air, oxygen and gas mixtures.</p>
1.4.8	Gas moisture content	<p>Excessive moisture affects the ability of most filtration systems to work effectively.</p> <p>Condensed moisture can also influence control valves, and result in accelerated corrosion in storage vessels.</p>	4	<p>Compressed air systems should be fitted with after-coolers to ensure that excess condensate is removed prior to storage.</p> <p>It is recommended that automatic drains be fitted to all filter housings.</p>

Chamber Oxygen Supply System Requirements

1.4.9	Oxygen supply volumetric or capacity considerations	<p>Correct volumetric considerations are essential for providing effective treatments, as well as preserving the health care facility's other requirements.</p>	<p>4</p> <p>3</p> <p>4</p>	<p>Required design considerations include:</p> <p>a) Required volume of oxygen to provide the maximum number of planned treatments between gas refilling.</p> <p><i>Note: One litre of liquid oxygen evaporates to ± 860 litres of gas at standard temperature and pressure (1 cf of liquid produces 860 cf of gas).</i></p> <p>b) Supply piping should be sized to support chamber maximum flow demand without affecting the health care facility's other requirements.</p> <p>c) Where liquid (cryogenic) oxygen is to be used, the supply company should do the appropriate storage tank sizing.</p> <p>As a guideline, a supply system should be based on the product of maximum number of occupants, breathing at least 64 actual lpm (2.3 acfm) at depth (in ATA), for the complete treatment cycle for the maximum intended number of treatments (per tank refill period).</p> <p>A 50% boil-off ratio is usually assumed and at least a 30% safety margin included.</p>
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1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
1.4.10	Emergency or back-up supply	Interruption of oxygen supply could compromise treatment as well as patient condition.	4	<p>A secondary (reserve) supply of oxygen should be provided in the event that the main service is interrupted.</p> <p>Use of limited quantities of HP oxygen, suitably regulated, is usually deemed sufficient.</p>
1.4.11	Chamber oxygen supply and exhaust systems	<p>An inadequate supply of therapeutic oxygen can compromise a treatment regimen and thus negatively affect the outcome for the patient.</p> <p>Exhaling oxygen or leakage from the breathing mask into the chamber, can elevate the chamber oxygen level above 23.5%, increasing the risk of fire.</p> <p>Failure of the overboard dump system may expose the patient or attendant to the risk of severe suction injuries.</p>	<p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>4</p> <p>4</p>	<p>The design of a chamber's supply and exhaust systems should meet the following criteria:</p> <p>a) It should be capable of ensuring a supply pressure of at least 0.35 MPa (50 psi) above the chamber's pressure to each outlet, or as otherwise required by the selected breathing apparatus;</p> <p>b) It should be equipped with emergency isolation valves, preferably fitted close to the shell;</p> <p>c) It should include sufficient capacity to permit treatments to be completed prior to refilling;</p> <p>d) Provide for a secondary (reserve) supply of oxygen in the event that the main service is interrupted;</p> <p>e) It should ensure that HP supplies conform to the guidelines for a safe and controlled supply;</p> <p>f) It should ensure that the exhaust system is fitted with an effective overboard dump process, which automatically adjusts to the treatment pressure; and</p> <p>g) It should ensure that the exhaust system has been designed to restrict or control the flow between the patient and ambient pressure.</p>
1.4.12	Cryogenic supply system	<p>Inadequate maintenance, poor housekeeping, and/or lack of regular inspection of the cryogenic supply system present a risk of fire, supply interruption, and/or facility damage.</p> <p>Even if the filling and maintenance of the system are</p>	<p>3</p> <p>3</p>	<p>If the facility has a cryogenic supply system, it should conform to all applicable statutes and regulations, should be controlled and managed by a competent gas supply company, and should be properly maintained, at a minimum with respect to these factors:</p> <p>a) The security of the site, to prevent unauthorized access or interference with the system;</p>

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Ref.	Element	Risks	RL	Minimum Requirements
	Cryogenic supply system (cont.)	handled by an outside vendor, the chamber facility's owners and managers still bear responsibility for ensuring the integrity, safety, and availability of the system.	<p>3</p> <p>4</p> <p>3</p> <p>3</p>	<p>b) Routine monitoring of fire hazards, such as removal of under- or overgrowth, overhead electrical supply lines, or burnable materials (including waste matter) stored in the immediate vicinity of the system;</p> <p>c) The placement and integrity of adequate warning signs and emergency instructions;</p> <p>d) Regular inspections (at least prior to each treatment session) of the cryogenic storage area, including monitoring of liquid/gas storage levels, system pressures, control positions, equipment condition, and site security; and</p> <p>e) Appropriate and regular maintenance by an appointed, competent gas supply company.</p>
1.4.13	Cryogenic system piping materials	Cryogenic operating temperature requirements compromise the strength and integrity of many standard materials.	4	<p>Materials used for liquid oxygen equipment should be selected on the basis of low temperature characteristics as well as compatibility and cleanliness.</p> <p>Copper, austenitic stainless steel and Monel are considered suitable.</p> <p>All pipeline designs should be undertaken and approved by a competent engineer.</p>
1.4.14	Oxygen purity standards	Impure or contaminated oxygen is a health as well as a fire risk.	<p>4</p> <p>3</p>	<p>a) Medical oxygen requires a purity level of at least 90%.</p> <p>Under no circumstances should a facility use oxygen that is not either piped from a cryogenic source, supplied from HP cylinders certified as containing medical-grade oxygen, or provided using a suitable medical oxygen generator.</p> <p>b) If a facility cannot be guaranteed of a suitably pure supply of oxygen, the supply to the chamber should be analyzed by one of these means:</p> <ul style="list-style-type: none"> • Continuously while online; • At the discretion of a competent person, who shall substantiate in writing the requirements for the frequency of the analysis; or • Whenever supplies are changed over or refilled.

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
Chamber Atmosphere Ventilation and Environment Requirements				
1.4.15	Ventilation requirements	<p>Inadequate ventilation can have an impact on patients' condition, allow a build-up of oxygen and/or carbon dioxide (CO₂), and affect the temperature and humidity in the chamber.</p> <p>Such conditions increase the risk of fire and/or toxic gas levels, as well as of other risks associated with elevated temperature and humidity.</p> <p>Such risks exist during all stages of chamber operation, including pressurization, a constant-pressure state, and depressurization.</p> <p>Poorly placed inlet and exhaust points may also result in inadequate circulation and ineffective removal of unwanted gases.</p>	<p>3</p> <p>3</p> <p>2</p>	<p>a) A minimum ventilation rate of at least 64 actual lpm (2.3 acfm)) per chamber occupant is required (<i>actual</i> flow implies the rated flow at the chamber's ambient pressure and temperature).</p> <p>This rate may be reduced if CO₂ levels are monitored continuously or if patients are breathing oxygen using an overboard dump system, providing that oxygen levels remain below 23.5%.</p> <p>The minimum ventilation rate should always be implemented when a mask is not being used by the patient(s) - such as during an air-break.</p> <p><i>Note: The ventilation rate may need to be increased above this recommended level if no overboard dump system is present, or if the overboard dump is not effective, in order to keep oxygen levels below 23.5%.</i></p> <p>b) Inlet and exhaust points should be located so as to ensure effective air circulation, scrubbing-out of unwanted gases, lowering of the chamber's internal temperature, and reduction of humidity levels.</p> <p>c) Stable conditions may be maintained using metabolic oxygen injection and scrubbing to remove CO₂ and odor levels.</p> <p><i>Warning: Under no circumstances should a chamber's interior oxygen level be allowed to exceed 23.5%.</i></p>
1.4.16	Conditioning of chamber air	<p>Uncomfortable temperatures within a chamber can compromise the patient's condition.</p> <p>Uncomfortable conditions can also heighten patients' anxiety levels, cause medical problems, and affect the control of static electricity.</p>	2	<p>Chambers should be maintained at a temperature under 30°C (86°F) and a relative humidity between 40% and 60%.</p> <p>This may be achieved through the use of ventilation using suitably conditioned air.</p> <p>Alternatively, suitably designed and approved chamber environmental conditioning units may be used.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
Air System Piping Requirements				
1.4.17	Gas supply pipe sizing	Incorrectly sized pipelines could compromise treatments, patient condition as well as the health care facility's other requirements.	3	<ul style="list-style-type: none"> a) Pipelines to the HBO treatment facility should be sized according to the maximum demand requirement - typically 20 mm (¾") for a 4 occupant chamber. b) Pipe length has a direct bearing on size, as pressure loss is directly proportional to length. c) Longer lengths may require compensation for pressure losses by increasing diameter. d) The system manufacturer usually specifies pressure available at the chamber. e) As a guideline, chambers require a minimum of 0.62 MPa (90 psi). f) Maximum pressure is usually limited to 5 MPa (72.5 psi). g) Air supply lines should have a safety shut-off valve adjacent to the treatment area and readily accessible to the facility personnel.
1.4.18	Chamber supply pressure	Visual indication of regulated gas supply to the chamber is necessary to ensure safe commencement of treatment, as well as during treatment.	3	<p>A downstream indicating pressure gauge, preferably mounted on the chamber control panel, should be fitted to allow visual monitoring at all times by the operator.</p> <p>Gauges should be checked at least once a year to ensure appropriate function (gauge should read zero where there is no supply pressure, and indicate the same supply pressure showing at the nearest supply point gauge, within a 10% deviation).</p>
1.4.19	Filtration	Dirt and construction debris may cause regulator failure, valve seat failure, calibration difficulties, poor or erratic chamber control, and even failure of critical control equipment.	3	<p>An in-line filter should be installed immediately prior to the chamber control system.</p> <p>A 10 µm filter, rated at 1.5 times the maximum line pressure, should be used.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.20	Oxygen toxicity	<p>Oxygen toxicity is a known contra-indication of this form of treatment.</p> <p>Planned air breaks reduce the susceptibility to oxygen toxicity.</p>	3	<p>All chambers should preferably be fitted with a breathing air supply system to allow patients to be switched to air at the onset of toxicity symptoms, as well as for the application of regular air breaks.</p>
1.4.21	Accidental mixing of gases	<p>Accidental mixing of oxygen and air will compromise the treatment efficacy, as well as compromise patients being treated for toxicity symptoms.</p>	4	<p>Gas supply systems should avoid common gas manifolds, where gas mixing can occur and should at least include dual check valves to prevent back-flow into each gas supply line.</p> <p>Proven-safe and rapid switchover systems are achieved by introducing air through a separate supply piping system direct to the patient using a face mask.</p> <p>Alternatives include valve interlocks or block-and-bleed piping arrangements to ensure that only one gas can be supplied to the chamber at any one time.</p>
1.4.22	Piping systems	<p>Certain piping materials are not suitable for hyperbaric facilities due to impurities and/or corrosion considerations.</p> <p>Undersized piping systems can affect patients and facility staff by prolonging treatments unnecessarily, restricting extraction of patients during emergencies, and generating excessive noise.</p> <p>Venting systems can cause injuries to patients if inlets are not suitably screened.</p>	<p>4</p> <p>3</p> <p>3</p> <p>3</p> <p>4</p>	<p>a) In most cases, only copper alloys, brass alloys, or stainless-steel alloys should be used for supply systems to a chamber (see 1.4.25 below for permissible exceptions).</p> <p>b) Materials for chamber exhaust systems are required to be oxygen-compatible but are not otherwise restricted.</p> <p>c) Supply piping systems should be designed to maintain compression rates between the ideal of ± 1.8 atm/min (27 psi/min) and a minimum of 0.34 atm/min (5 psi/min). The industry average is generally taken as 1 atm/min (14.7 psi/min).</p> <p>d) Multiplace chambers should be capable of complete decompression from 3 ATA (29 psi to the surface in less than 6 minutes.</p> <p>e) All exhaust inlets, relief valves, depth monitoring inlets, sample inlets, and other suction inlets inside the chamber should be fitted with anti-suction-injury devices.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
	Piping systems (cont.)	<p>Malfunctioning, leaking, damaged or seized valves allowing gas to flow either into or from the chamber may lead to uncontrollable pressurization or depressurization.</p> <p>This could occur either insider or outside the chamber.</p> <p>Although unlikely, in the case of abandonment (accidental or deliberate), the chamber attendant may be unable to bring the chamber to the surface.</p> <p>The use of HP supplies can result in the overpressurization of piping and/or other components, beyond their rated levels.</p> <p>Inadvertent overpressurization can also occur if the control equipment fails or if the operator fails to control pressures correctly.</p> <p>Dirt particles are a known source of the failure of regulators to maintain constant downstream pressure.</p> <p>System designs that rely on operator attentiveness to prevent certain actions – including back-filling of storage vessels at different content levels, reverse-pressure or -flow situations (especially on systems with diaphragms and/or sensing equipment) and venting through unintended flow paths – can compromise supplies, lead to an inaccurate assessment of available gases, and/or result in the failure of pressure-control equipment.</p>	<p>2</p> <p>4</p> <p>3</p> <p>3</p> <p>4</p> <p>3</p>	<p>f) All shell penetrations should be fitted with internal and external isolating valves, as close to the penetration as possible, to allow the gas flow to be shut off in the event of a malfunction.</p> <p>It is accepted that modern, automatically-controlled systems do not provide for this feature.</p> <p>The Safety Officer will need to make an appropriate risk-mitigating decision in this regard.</p> <p>g) Piping systems should be configured with an escape valve device, so that occupants of the chamber can override the controls in the event of operator failure and return the chamber to surface pressure.</p> <p>h) Chambers should be pressurized using only regulated, low pressure (LP) gas.</p> <p><i>Note: HP gas supplies, i.e., those > 4 MPa (580 psi), should be reduced as close to the source as practical.</i></p> <p>i) All pressure-reducing regulators should be fitted with downstream pressure-relief devices in order to protect any piping and/or other components that are rated for lower pressures.</p> <p>j) The inlets on all pressure-reducing regulators should be fitted with suitably sized particle filters (< 10 µm) to prevent dirt or debris from entering the sensing ports and causing downstream regulator creep.</p> <p>k) The piping of supply systems should be fitted with nonreturn (check) valves to prevent the following actions:</p> <ol style="list-style-type: none"> 1) inadvertent back-filling of storage vessels; 2) exposure of regulators and/or other components to reverse-pressure situations if they were not designed for such applications; and 3) venting through self-venting ports on pressure-reducing regulators.

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Ref.	Element	Risks	RL	Minimum Requirements
	Piping systems (cont.)	Inappropriate or inadequate cleaning procedures can result in premature component failure or the introduction of toxic vapors into the chamber and can increase the risk of fire.	3	l) All air-system components and piping should be suitably cleaned prior to their first use.
		Computer or remote-control pneumatic systems are complex and failures, no matter how unlikely, could result in loss of control.	3	m) All computerised or remote-control pneumatic systems should be designed with an adequate back-up system, as well as manual overrides for all remotely controlled valves.

Oxygen System Piping Requirements

1.4.23	Oxygen piping	Compressed oxygen represents a risk of fire and other effects of its stored energy.		Oxygen piping should be designed and installed according to the following minimum requirements:
			4	a) Only competent and thoroughly trained individuals should install, clean, or work on oxygen piping systems.
			3	b) Only copper alloys, brass alloys, or stainless-steel alloys should be used for oxygen supply systems to a chamber (see 1.4.25 below for permissible exceptions).
		Inappropriate or inadequate cleaning procedures can result in premature component failure or the introduction of toxic vapors into the chamber and can increase the risk of fire.	3	c) Materials for chamber exhaust systems are required to be oxygen-compatible but are not otherwise restricted.
			4	d) If copper tubing is brazed, it should be continuously purged with nitrogen during the brazing process to prevent the formation of hazardous copper oxides.
			4	e) All oxygen supply lines should be cleaned in accordance with an approved oxygen cleaning procedure.
		Certain piping materials are not suitable for use with oxygen.	3	f) Only oxygen-compatible materials should be used (publications of the ASTM [American Society for Testing and Materials], CGA [Compressed Gas Association], and ASME/PVHO contain lists of approved materials).
		In the event of a fire, the oxygen supply to the chamber would likely exacerbate the fire.	4	g) An oxygen shut-off valve should be installed at the point where the oxygen enters the room.

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Ref.	Element	Risks	RL	Minimum Requirements
	Oxygen piping (cont.)	<p>Rapid acting valves are a potential source of adiabatic heating during opening and closing.</p> <p>The use of HP supplies can result in overpressurization of piping and other components not intended for elevated pressures.</p> <p>High pressures can also be introduced inadvertently if control equipment fails or if an operator fails to control pressures correctly.</p> <p>Dirt particles are a known source of the failure of regulators to maintain constant downstream pressure.</p> <p>System designs that rely on operator attentiveness to prevent certain actions – including back-filling of storage vessels at different content levels, reverse-pressure or -flow situations (especially on systems with diaphragms and/or sensing equipment), and venting through unintended flow paths – can compromise supplies, lead to an inaccurate assessment of available gases, and/or result in the failure of pressure-control equipment.</p> <p>Piping joints, both welded and re-useable connections, are known areas where oxygen under pressure can leak out.</p>	<p>4</p> <p>3</p> <p>3</p> <p>4</p> <p>3</p> <p>3</p> <p>3</p>	<p>h) Quick-acting ball valves may be used to isolate LP oxygen lines, i.e., < 0.86 MPa (125 psi). Quick-acting ball valves should not be used to isolate lines containing oxygen at pressures above 0.86 MPa (125 psi).</p> <p>i) HP oxygen supplies, i.e., those > 4 MPa (580 psi) should be reduced at their source or, if that is impractical, at the chamber control station.</p> <p>j) All pressure-reducing regulators should be fitted with downstream pressure-relief devices in order to protect piping and other components rated for lower pressures.</p> <p>k) The inlets on all pressure-reducing regulators should be fitted with suitably sized particle filters ($\leq 10 \mu\text{m}$) to prevent dirt from entering the sensing ports and causing downstream regulator creep.</p> <p>l) Oxygen supply systems should be fitted with nonreturn (check) valves to prevent the following actions: inadvertent back-filling of storage vessels; exposure of regulators and/or other components to reverse-pressure situations if they were not designed for such applications; and venting through self-venting ports on pressure-reducing regulators.</p> <p>m) Following its installation, and at prescribed maintenance intervals, all oxygen piping should be tested for leaks (caution should be exercised when using nonoxygen-compatible or flammable test solutions); and</p> <p>n) Only special, dedicated tools should be used for oxygen service (i.e., they should be clean and nonsparking).</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.24	Oxygen exhaust system	<p>Uncontrolled exhaust of oxygen constitutes a physiological and fire risk.</p> <p>Back-pressure may be caused by inappropriate design and slow the duration of ascent; this is specifically hazardous in the event of an emergency situation requiring rapid depressurization.</p>	<p>4</p> <p>4</p> <p>4</p> <p>4</p> <p>3</p> <p>4</p>	<p>The design of the exhaust equipment, including the discharge from any safety-relief device(s) into an enclosed space or into the chamber room, should be connected to an exhaust line piped into a safe open space. (Ref. also 1.8.2)</p> <p>In addition, the exhaust system should:</p> <p>a) Be fitted with emergency isolation valves, preferably fitted close to the chamber shell;</p> <p>b) Contain a line length of no longer than 5 m (16 ft) unless sized to eliminate gas flow back-pressure;</p> <p>c) Preferably be separate from any other exhaust lines;</p> <p>d) Contain no flow obstructions at or near the outlet;</p> <p>(e) A screen at the outlet should be considered to prevent birds and insects from entering and causing obstructions, such as nests.</p> <p>Where exposed to rain, the outlet should face down; and</p> <p>(f) Not terminate near a source of heat, an ignition sources, or a hazardous area.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.4.25	Flexible hoses	<p>Due to more frequent connection & disconnection, and/or an intrinsically weaker structure, flexible hoses are more prone to failure due to mechanical damage, surface abrasion, material age- or environmental related degradation and cracking, and weakening of end fittings.</p> <p>Any of these can result in a rapid and even catastrophic failure, with the associated expansion-related damage, or unrestrained hoses whipping around and cause significant damage.</p>	3	<p>In selected cases, the use of flexible hoses for gas supply systems is acceptable, subject to the following criteria:</p> <ul style="list-style-type: none"> • Be kept to a minimum, except for low pressure exhaust lines; • Preferably be restricted to short lengths [<1 m (3 ft)] where used for HP [>4 MPa (580 psi)] gas applications; • Where longer lengths need to be used, these should be fitted with restraints (anti-whip devices); • Be suitably rated and appropriately certified for the system design pressure; • Be consistent with cleanliness requirements and compatible with the gas they will transport; • Be connected without any stress on joints and couplings; • Be assembled without kinks or sharp bends; • Be adequately protected from external, mechanical damage; • Not pose a trip hazard; • Be used only where adequate provision has been made for the regular inspection of the condition of all flexible hoses; • Shut-off valves should be located as close to the chamber as is practical; and • Consideration may be given to the use of a check valve in a flexible hose connected directly to a chamber, as a buffer in the event of a line break.
Breathing Apparatus				
1.4.26	Internal breathing apparatus	<p>Toxic, nonbreathable, and harmful gases constitute a serious hazard for occupants of a chamber.</p> <p>An ineffective supply of therapeutic gas can compromise the quality of the treatment and affect the outcome for the patient.</p>	4 4 4	<p>Each occupant should be provided with an individual breathing apparatus.</p> <p>The apparatus, including its supply system, should be designed to meet the following criteria:</p> <ul style="list-style-type: none"> (a) it is independent of the chamber atmosphere; (b) it is fully functional at all chamber operating pressures;

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Ref.	Element	Risks	RL	Minimum Requirements
	Internal breathing apparatus (cont.)		4	(c) where a demand system is used, it is capable of sustaining a supply pressure of at least 0.35 MPa (50 psi) above chamber pressure;
			4	(d) it can be used simultaneously by all occupants;
			4	(e) where a mask exhaust system is used, it is fitted with an effective overboard dump system, which automatically adjusts to treatment pressure and includes some type of vacuum relief;
			5	(f) it is available for immediate use at all times; and
			4	(g) in the event of a fire, the supply can be switched to air (or a suitable, normoxic mixture).
1.4.27	External self-contained breathing apparatus	<p>In the event that the air in the vicinity of a chamber becomes fouled by smoke or other combustion products, the chamber operator may (due to the complexity of the treatment then in process) be unable to depressurize the chamber and evacuate the occupants to safety.</p> <p>In such a case, the operator faces the risk of breathing the fouled air unless an external self-contained breathing apparatus is available.</p>	4	<p>An independent source of breathing air or a suitable filtered breathing apparatus should be available for use by essential chamber personnel in the event that the air in the vicinity of the chamber is rendered toxic, is fouled, or otherwise becomes unbreathable.</p> <p>Suitable eye protection to shield chamber personnel from combustion products should be incorporated into the breathing apparatus.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
General Gas System Requirements				
1.4.28	Sound attenuation	The chamber environment presents numerous acoustic problems that serve to magnify noise levels.	3 3 2 4	(a) Mufflers should be used to reduce noise to the levels required by national regulations, or at least below 85 dB(A). (b) Noise levels during maximum flow situations, including emergency ascents, should be considered and verified. (c) Reverberation should be reduced through the use of baffling panels. (d) If noise levels cannot be effectively reduced (such as during pressurization), personal ear protection should be provided to all chamber occupants.
1.4.29	Power-operated or automatic chamber control system	Automatic control systems may provide better control and allow the operator to focus on the patient rather than the controls. In the event of any system failures, the chamber and the occupants may be placed at risk from rapid ascent or descent. This could also affect occupants being locked in the chamber.	4	The chamber operator must have the means to override or deactivate the control system to manually control the chamber. This should include descent, ascent, ventilation rates, as well as maintaining the chamber at constant treatment pressure.

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Ref.	Element	Risks	RL	Minimum Requirements
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1.5 Fire Protection

1.5.1	Fire-suppression system	A fire within a hyperbaric chamber presents a potentially fatal and catastrophic situation.	5	<p>a) Independently supplied deluge and handline fire-suppression systems are the preferred fire protection options.</p> <p>This is usually mandatory for HBO chambers, but is not always the case in different countries.</p> <p>Some countries do not mandate the requirement for an independent handline fire-suppression system, and allow for portable hyperbaric fire extinguishers to be used.</p> <p>The number and positioning of portable extinguishers depend on chamber size and configuration.</p> <p>Portable hyperbaric fire extinguishers should be rated for the maximum treatment pressure.</p>
<p><i>Comment: It is normally mandatory for chambers to have both handline and deluge fire-suppression systems; however, the deluge system may be activated either manually or automatically, at the discretion of the facility's Medical Director and/or Safety Officer.</i></p> <p><i>Factors that should be considered in making that determination include the type of medical procedures conducted at the facility and the resulting risk to patients in the event that an automatic system is accidentally triggered.</i></p> <p><i>With the exception of oxygen-fueled fires, most fires within a chamber can be effectively extinguished using a manual handline.</i></p> <p><i>Thus additional relevant factors include the effect on likely reaction times of the chamber's physical layout; the ease of access to the chamber; the chamber's size (which can affect how fast the chamber environment is oxygen-enriched in the event of a leak); the response time of the chamber's oxygen monitoring systems; and the likelihood that potentially hazardous equipment (e.g., a defibrillator) may need to be used within the chamber.</i></p>				
1.5.2	Component failure	Component failure can affect the integrity of a fire-suppression system.	5	The design of all fire-suppression systems should be such that failure of components in either the deluge system or the handline system will not compromise the effective functioning of the other system.

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Ref.	Element	Risks	RL	Minimum Requirements
1.5.3	Automatic activation of functions	<p>The activation of certain safety-related functions cannot be left to the operator during emergency situations.</p> <p>Without immediate reactions to such an event, the lives of occupants and the safety of the entire facility could be placed at extreme risk.</p>	<p>4</p> <p>4</p> <p>5</p> <p>4</p> <p>3</p> <p>4</p>	<p>On activation of either a deluge system or a handline system, the following should occur automatically.</p> <p>Where a facility does not have an automatic feature, an appropriate emergency action plan should include all of these steps.</p> <p>a) Visible and audible indication of an alarm situation at the operator’s console, plus signaling to the nearest fire department;</p> <p>b) Instruction to the occupants to immediately put on their breathing apparatus;</p> <p>c) Isolation of all oxygen supplies to the chamber’s interior and activation of an oil-free breathing air supply (or normoxic gas) in the place of oxygen;</p> <p>d) Disconnection of all internal, ungrounded electrical power systems, excluding those that are intrinsically safe;</p> <p>e) Activation of emergency lighting and communications, if applicable; and</p> <p>f) Based on severity, and where the situation can be safely assessed:</p> <ul style="list-style-type: none"> • Surfacing of the chamber as rapidly as the situation requires; and • Performance of any other special activities within the chamber.
1.5.4	Automatic fire alarm	<p>The chamber operator should not be expected to have to contact fire and/or emergency services manually if an adverse incident occurs either within the chamber or in its immediate vicinity.</p>	5	<p>A fire alarm and/or emergency signaling device should be located at the operator’s console, so the operator can easily and directly signal either a telephone operator at a nearby health-care facility.</p> <p>A direct alarm/monitoring system automatically coupled to the fire department is even better.</p>
1.5.5	Unsuitable means of fire extinguishment	<p>Certain generally accepted methods of extinguishing a fire are not suitable or effective within a hyperbaric, oxygen-enriched environment.</p>	5	<p>Fire blankets, CO₂ extinguishers, and other fire-extinguishing devices that rely on air exclusion are either unsafe or ineffective in an oxygen-enriched environment and thus should not be installed in or carried into a chamber.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.5.6	Fire-suppression system's power supply	A power failure could completely compromise the activation and effective functioning of the fire-suppression system.	5	All fire-suppression system components and controls should be powered from the hyperbaric facility's emergency power system or, from the independent backup power reserve.
1.5.7	Water deluge system	<p>Unless the deluge system is properly designed, there is a risk that its coverage and/or function may be ineffective under the range of pressures and situations found within a hyperbaric environment.</p> <p>Fire deluge tanks are not usually fitted with the means to determine the actual water level.</p> <p>The required pressurized space above the water implies that the vessel cannot simply be filled to the top.</p> <p>Any rust or other particles and flakes may clog the spray nozzles or cause the activation valve to seize shut.</p>	<p>5</p> <p>5</p> <p>5</p> <p>3</p> <p>3</p>	<p>a) A fixed water deluge system is required in all manned locks, excluding locks used solely for transfer purposes.</p> <p>b) The system should be designed so as to function effectively and simultaneously in all treatment locks, even at different pressures.</p> <p>c) The system should perform as specified across the full operating pressure range of the chamber.</p> <p>d) A suitable water-level indicator should be installed and preferably displayed at the chamber console.</p> <p>e) A suitable water filter (strainer) should be installed as close to the outlet of the water-supply system, before reaching the deluge activation system (e.g. fast-acting valve)</p>
1.5.8	Location of activation controls	Response time during an emergency has a direct effect on the success of the outcome.	<p>4</p> <p>3</p>	<p>a) Activation and deactivation controls should be installed at the operator's console and inside each manned lock.</p> <p>The number and location of control stations required inside each lock are dependent on the lock size and are subject to the Safety Officer's discretion.</p> <p>b) All controls should be designed to prevent their inadvertent activation, but not cause a delay if activation is required.</p>
1.5.9	Deluge activation time	The speed with which a deluge system is activated in the event of a chamber fire has a direct effect on the success of the outcome.	<p>4</p> <p>4</p>	<p>a) Deluge valves should open within 1 second of the activation signal.</p> <p>b) Water should be delivered from the sprinkler heads no longer than 3 seconds after the activation signal.</p>
1.5.10	Adequate deluge system coverage	Inadequate or incomplete coverage reduces the effective extinguishing capability of a deluge system.	4	a) The deluge system should be designed so that the number and position of the sprinkler heads achieve the following effects:

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Ref.	Element	Risks	RL	Minimum Requirements
	Adequate deluge system coverage (cont.)			<ul style="list-style-type: none"> • Uniform spray coverage; • An <i>average</i> spray density at <i>floor level</i> of no less than 82 lpm/m² (2 gpm/ft²); and • An actual coverage of no less than 41 lpm (1 gpm) over any floor area larger than 1 m² (1 ft²). <p>4 b) The design should account for the fact that the increased density of air in a hyperbaric atmosphere causes increased resistance to water droplet movement, which in turn reduces the effective spray angle – thus necessitating a greater number of sprinkler heads.</p> <p>5 c) The system should be tested after it has been installed, as well as after any modifications are made, preferably across the full range of operating pressures, to confirm that it functions as designed.</p>
<p>Definition: The term “floor level” in the context of a horizontal, cylindrical chamber is taken to mean either the area one-quarter diameter below the chamber’s center line (which equates to 87% of the chamber diameter), or the area at actual floor level, whichever is greater.</p> <p>Caution: Conventional deluge systems as found in many diving systems are not necessarily appropriate for high-temperature and rapidly propagating oxygen fires that could potentially occur in HBO facilities.</p>				
1.5.11	Deluge system water capacity	<p>Insufficient water capacity, especially if all spray nozzles are operating simultaneously, can compromise the effective extinguishing capability of a deluge system.</p> <p>Excessive amounts of deluge water could present a drowning risk where chamber occupants have fallen to the floor, or failure of essential equipment due to flooding.</p> <p>In the event that the deluge water is depleted, driving gas may enter the chamber, causing an increase in chamber pressure.</p>	<p>4</p> <p>4</p> <p>3</p>	<p>a) The system should be designed with sufficient water capacity to maintain the required flow, which is determined as the product of 82 lpm over the actual floor area in m² (2 gpm/ft²) in each chamber lock for at least 1 minute.</p> <p>b) The maximum water capacity should be determined by the capacity of the chamber’s bilge or drainage system, so as not to flood equipment or, in extreme cases, drown a patient who may have fallen to the floor.</p> <p>c) The driving gas supply should shut off prior to water being driven out of the deluge supply tank.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.5.12	Reserve supply pressure	Insufficient reserve supply pressure will render the deluge system ineffective in the event of a power failure.	4	The deluge system should have sufficient stored pressure and volume of gas to operate for a minimum of 15 seconds without electrical power.
1.5.13	Hand line extinguishing systems	Smaller fires can be extinguished using handlines, avoiding the disruptive effects of a deluge system. Inadequate handline systems can result in more damage than necessary.	3 3 3 3	a) Each treatment lock should be fitted with at least two handlines. b) If a treatment lock is designed for only one or two patients and is fitted with just a single handline, the handline should reach the entire interior of the chamber safely, including the bilge, if applicable. c) All transfer locks should be fitted with at least one handline or one portable hyperbaric fire extinguisher. d) If bilge access panels are installed, at least one handline should be long enough to extinguish fires in the bilge area.
1.5.14	Handlines	Inadequately sized or rated handlines can fail during use, which both causes a physical hazard and compromises their effectiveness.	3 4	Handlines should have a minimum internal bore of 12 mm (½”). All handlines should have a rated working pressure greater than the pressure for which the supply system is designed.
1.5.15	Handline activation	Cumbersome, awkward, or illogical activation of handlines can impair response times.	4	Hand lines should be activated using individual, quick-opening valves located within each chamber lock.
1.5.16	Dual valves	Leaking activation valves can present problems inside a chamber for electrical equipment, patients, etc.	3	All handlines should be fitted with individual override valves that are placed in accessible locations outside the chamber and are sealed in the open position with frangible safety wire seals.
1.5.17	Water supply pressure and/or flow	Inadequate pressure and/or flow in the water supply will impair the effective functioning of handlines.	3 3	a) The pressure of any handline water supply should be at least 0.35 MPa (50 psi) higher than the chamber pressure at all times. b) The system should be capable of delivering at least 19 lpm (5 gpm) per handline at maximum chamber pressure.
1.5.18	Automatic fire detection	Detectors that are incorrectly specified or fail to operate properly can compromise the effectiveness of the fire-suppression system.	3	If a system is fitted with automatic fire detectors, they should conform to the following criteria: a) Only surveillance detectors, which respond to flame radiation within 1 second of flame origination, should be used;

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Ref.	Element	Risks	RL	Minimum Requirements
	Automatic fire detection (cont.)		3 4 4 3	<p>b) The number and physical location of detectors should be based on the sensitivity of each detector and on the configuration of the space(s) under protection (without any blind spots);</p> <p>c) The detectors should be powered by the chamber's backup system or be fitted with an independent backup battery;</p> <p>d) If the detectors are used to activate the deluge system automatically, the requirements for manual activation and deactivation, as well as required response times, still apply; and</p> <p>e) The system should be designed with self-monitoring for fault detection, as well as fault alarms and indicators.</p>
1.5.19	Regular function testing	<p>Deluge systems that are not regularly maintained and functionally tested can fail upon use.</p> <p>Seals, controls, pressurization devices, etc. can stick or jam due to creep, embrittlement, or deterioration.</p>	4 4	<p>a) Deluge and handline systems should be function tested at least every six months, with their full and effective function confirmed.</p> <p>b) If a bypass system is installed, the design of the system's test mode should be such that the system resorts to normal operating mode by default after the test.</p> <p>This requirement does not replace the need for full function and performance testing after a system's initial installation and after any subsequent modifications.</p>
	<p><i>Recommendation: Bypass systems make regular testing easier, as the interior of the chamber does not need to be deluged.</i></p> <p><i>Care should be exercised in the selection of a bypass system, so that the potency of the full flow path can be assessed.</i></p> <p><i>Lines may become blocked over time, reducing the supply of water to individual sprinkler heads.</i></p> <p><i>It may be preferable to design a bypass so that full flow is achieved but the water is captured by means of flexible pipes leading down to the bilge (preferably into suitable containers).</i></p> <p><i>It is also still advisable to measure the system's flow (volume per unit of time) to ensure that full flow is achieved, in accordance with the system's design.</i></p> <p><i>The duration of the sprinklers' operation will depend on the system's design but generally should be no less than 15 seconds.</i></p>			

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Ref.	Element	Risks	RL	Minimum Requirements
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1.6 Electrical Systems

	<p><i>Warning: Electrical equipment that must be installed in or brought into a chamber should be limited to a maximum voltage of 24 V_{DC}.</i></p> <p><i>Higher voltage equipment that needs to be installed should comply with the safety requirements specified where an AC power is required to be used.</i></p> <p><i>All of the precautions detailed below should still be followed, as even low-voltage switches can induce sparks with enough energy to ignite certain materials under normal conditions.</i></p> <p><i>Note: A hyperbaric chamber is considered a Class 1, Division 2 location for the purposes of specifying electrical system components. That means it is a location in which flammable vapors are present but are normally confined within closed systems, or in which ignitable concentrations of such substances are limited by ventilation. In other words, a hyperbaric chamber is considered a Class 1 location not because of its oxygen-enriched atmosphere; rather it is the presence of flammable vapors (e.g., from alcohol swabs or medical dressings), combined with the presence of combustible materials (including human skin), that necessitates the specification of Class 1 requirements for a chamber's electrical system.</i></p>			
1.6.1	Electrical regulations	<p>The presence of electrical wiring and equipment within chambers presents several critical risks, including fire.</p> <p>It is essential to precisely follow local electrical regulations during construction and/or renovation of a chamber system, as they are devised to meet local operating and supply conditions.</p>	4	<p>NFPA 70, the National Electrical Code, contains applicable regulations that have been considered by the NFPA 99 committee.</p> <p>All electrical work on a chamber should adhere to either this code or, at a minimum, to local electrical regulations applicable to alternating current (AC) distribution and wiring.</p>
1.6.2	Location of service equipment, switchboards, distribution boards, and/or control panels	Switching for all forms of electrical power can produce sparks that contain more than sufficient energy to ignite a flammable material.	4	All electrical service equipment and high-voltage equipment (i.e., above 24 V _{DC}) should be located outside of the chamber.
1.6.3	Energised electrical equipment built into oxygen-piped consoles	The combination of leaking oxygen piping and energised electrical equipment will produce an explosion or fire hazard.	4	If control consoles contain both oxygen piping and electrical equipment, the electrical equipment should be totally enclosed or constantly ventilated, or the enclosed console space should be either ventilated or monitored for excessive oxygen concentrations.

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.4	Location of switches, switch panels, circuit-breakers, line-fuses, relays, ballasts, motor controllers, transformers & power supplies	<p>Switching of all forms of electrical power, even low power, can produce sparks.</p> <p>Energy storage devices can produce sparks when switched or rapidly discharged.</p> <p>Sparks are a proven source of ignition.</p>	<p>4</p> <p>4</p> <p>4</p> <p>3</p>	<p>a) No switching devices and no power sources should be installed within a chamber.</p> <p>b) Power supplies for equipment inside a chamber should be installed outside the chamber, according to the following criteria:</p> <ul style="list-style-type: none"> • For AC power, an ungrounded isolated power supply (IPS) should be used; and • For direct current (DC) power, an appropriately shielded transformer providing ungrounded power and including suitable protection (a fuse, trip switch, or circuit breaker) to protect against any current overload should be used. <p>c) If switches need to be installed, intrinsically safe housings (i.e., rated for explosive environments) are required unless the switching capacity is < 25 mW (e.g., piezo switches).</p> <p>d) Portable items of equipment may be used inside a chamber only if they are certified as intrinsically safe or have been assessed as safe by the Safety Officer.</p>
1.6.5	Electric motors	<p>Electric motors, including both conventional commutating motors as well as brushless motors, are a source of sparks and/or localized high temperatures.</p>	4	<p>Fan motors should be mounted outside of the chamber.</p> <p>Motors specifically designed and certified for use within hyperbaric environments may be considered (e.g., for CO₂ scrubbers or noninvasive blood pressure monitors), with the written approval of the Safety Officer.</p> <p>Acceptable motors include explosion-proof motors, purged or gas-filled motors, and motors that can be demonstrated to be localized heat-source-free and arc-free.</p>
1.6.6	Protection from water deluge	<p>Electrical equipment that is exposed to immersion or flooding by either external or internal sprinkler and/or deluge systems can fail.</p> <p>Patient outcomes and safety procedures can thereby be affected.</p>	5	<p>All critical electrical equipment should be protected from the effects of water-based fire-suppression systems.</p> <p>If that is not possible, any equipment critical to safety should be able to function long enough to allow patients to be decompressed if necessary.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.7	Reserve power supplies	<p>If critical equipment fails due to a building or municipal power failure, the health and safety of chamber occupants can be compromised if lighting and communications systems fail.</p> <p>The chamber environment may become hazardous while monitors are down, patient monitoring equipment may fail, safety equipment may be rendered inoperable, and the chamber may not be able to be safely decompressed.</p>	<p>4</p> <p>5</p> <p>4</p>	<p>a) All critical equipment – including chamber lighting and emergency lighting, communications equipment (including emergency communications, if applicable), alarm systems, fire detectors, fire-suppression systems, chamber pressure controls and monitors, patient monitors, infusion pumps and ventilators, and environmental monitors – should be connected to either a health-care facility’s emergency electrical system or, preferably, an independent reserve supply facility.</p> <p>b) If automatic controls are used to control chamber pressure, pressurization, and depressurization, power to these controls should be maintained for a sufficient time to complete a treatment or at least to depressurize the chamber safely.</p> <p>In addition, a full manual set of controls should be provided.</p> <p>c) Emergency or backup lighting to the facility should be provided.</p>
1.6.8	Reserve gas supplies	<p>Failure of compressed air systems and/or oxygen supply systems due to a power outage can compromise the chamber environment (due to insufficient ventilation) and can endanger patient safety (e.g., due to ventilator failure, oxygen supply interruption, etc.).</p>	<p>4</p> <p>4</p> <p>4</p>	<p>a) If only low-pressure compressors are used, at least one compressor should be connected to an emergency power system.</p> <p>b) Stored HP air supplies may be used to alleviate such a situation; however, the amount of stored air should be such that a treatment can be safely concluded without compromising the patient’s safety.</p> <p>c) Stored HP oxygen may be used as a backup for liquid oxygen (LOX) supplies.</p>
1.6.9	Integrity of control and alarm systems	<p>Power outages, especially those due to spikes or variations in voltage, can compromise the function of control systems and alarms.</p> <p>This may lead to improper deluge activation, false alarms, loss of chamber pressure control, etc.</p>	<p>4</p>	<p>Chamber control and alarm systems should be so designed that hazardous conditions cannot occur during power variations or interruptions or during power restoration.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.10	Chamber wiring and/or equipment	<p>Inappropriate electrical wiring and unsuitable electrical equipment can present a risk of explosion, electrocution, or implosion in a chamber environment.</p> <p>Contact with electrically live components can affect the human body in the following ways:</p> <ul style="list-style-type: none"> • Tetanization, or the involuntary contraction of affected muscles, which can make it difficult to let go of a live component.[¶] • Breathing arrest, due to involuntary contraction of the muscles that control the lungs, which can alter normal respiratory processes.[¶] • Ventricular fibrillation, or the superposition of an external current with physiological currents leads to uncontrolled contractions and this induces alterations of the cardiac cycle.[¶] • Burns, due to heating caused by current passing through the body.[‡] <p>¶ AC power ‡ AC or DC power (the Joule effect)</p>	<p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>5</p> <p>3</p>	<p>a) The requirements for Class 1, Division 2, locations should be followed as a general rule for any electrical wiring and equipment located in a chamber.</p> <p>This does not classify the chamber as a Class 1 location.</p> <p>b) NFPA 70, Article 500, provides guidance on selecting equipment and designing wiring for chamber environments.</p> <p>c) Only the minimum amount of electrical equipment deemed necessary for patient care (as determined for each treatment) should be permitted inside a chamber.</p> <p>A chamber should not be used to store electrical equipment not required during treatment.</p> <p>d) All equipment intended for use within a chamber should be tested and approved for such use.</p> <p>e) Conductive surfaces of all electrically powered equipment should be grounded to the chamber shell.</p> <p>f) Standard medical industry equipment should not be altered for use inside a chamber unless such alterations are sanctioned by the original manufacturer or by a competent authority.</p> <p>g) The chamber's oxygen level should be continually monitored, and alarms should be sounded when it rises above 23.5%.</p> <p>h) Advice from a competent electrical design authority should be sought to ensure safety and compliance with these requirements.</p>
1.6.11	Insulation of conductors	<p>Uninsulated conductors represent a source of sparks. The composition of insulating material may also present an environmental hazard if it's exposed to heat or fire.</p>	<p>3</p> <p>3</p> <p>3</p>	<p>All conductors used inside a chamber should be insulated using a flame-resistant material.</p> <p>a) Ground conductors encapsulated within equipment, or wiring that is an integral part of approved equipment, do not require insulation.</p> <p>b) Wiring that is an integral part of equipment approved for use inside a chamber does not need to meet the flame-resistance classification.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.12	Wiring methods	Inadequate wiring methods can generate heat, shorting, and/or burn-through, which can cause sparking or ignition.	<p>3</p> <p>3</p> <p>3</p> <p>4</p>	<p>a) Fixed wiring should comply with the requirements of Class 1 Division 2.</p> <p>b) Wiring that is classified as intrinsically safe should be permitted in conventional locations.</p> <p>c) If fixed conduits, boxes, and enclosures are used, they should be approved as explosion-proof for Class 1, Division 1, locations.</p> <p>d) Decisions regarding the suitability of wiring methods should be made by a competent person.</p>
1.6.13	Sealing and drainage of conduits and enclosures	<p>Activation of a deluge system can introduce water into unsealed enclosures.</p> <p>This can lead to premature failure of electrical wiring and components.</p>	3	<p>Where fixed conduits or non-sealed electrical enclosures are used, adequate draining should be provided.</p> <p>Requirements regarding sealing and drainage are detailed in NFPA 70, Article 501-5, and should be followed.</p>
1.6.14	Flexible cords used with portable equipment	The interruption of any powered circuit, even for low voltages, can produce a spark.	<p>3</p> <p>3</p> <p>4</p> <p>3</p>	<p>The cords used with portable equipment must meet the following criteria:</p> <p>a) They must be of a type approved for extra-hard utilization;</p> <p>b) They must include a ground conductor;</p> <p>c) They must be connected to terminals in a secure and approved manner; and</p> <p>d) They must be supported in such a manner that no tension exists on the terminal connections.</p> <p>The only exception to these rules applies to cords normally supplied with portable devices that are rated at less than 2 A, where such cords are securely fastened and protected from accidental damage.</p> <p>In addition, the device should have an on-off power switch outside the chamber and the plug on the cord should not be used to interrupt power.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.15	Receptacles and plugs	<p>Interruption of any powered circuit can produce sparks sufficient to ignite a flammable agent.</p> <p>Unsecure and ungrounded connections are a possible source of shock and arcing.</p> <p>Drenching from a deluge system can cause short circuits in unprotected connectors.</p>	<p>4</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p>	<p>All plugs and receptacles should meet the following criteria:</p> <p>a) They should be of an approved type;</p> <p>b) They should be grounded via a grounding conductor;</p> <p>c) They should be fitted with an interlocking mechanism to prevent withdrawal or insertion while they are energized;</p> <p>d) They should be fitted with a locking mechanism or be supplied with a label warning against unplugging them while they are under load; and</p> <p>e) They should be secured and protected against accidental damage by chamber occupants.</p>
1.6.16	Internal switches	<p>Switches are a potential source of sparking.</p>	<p>4</p> <p>4</p> <p>4</p>	<p>It is recommended that all switches be located outside the chamber.</p> <p>If internal switching is necessary, it should be achieved using intrinsically safe circuitry that drives external power and control circuits.</p> <p>If internal switches are used, they should meet one of the following criteria:</p> <p>a) They should be waterproof; or</p> <p>b) They should either be housed in an enclosure so that no sparks can reach the chamber atmosphere or be rated as intrinsically safe.</p>
1.6.17	Monitoring of equipment temperature rating	<p>Hot surfaces can be a source of ignition, especially within chamber environments.</p>	<p>4</p>	<p>No equipment installed or allowed in a chamber should have any exposed surfaces exceed a temperature of 85°C (185°F).</p> <p><i>Note: This temperature threshold is based on the ignition temperatures of materials commonly found inside HBO chambers, on the potential for fault conditions in oxygen-enriched atmospheres, and on consideration for the safety of chamber occupants.</i></p>
1.6.18	Exposed live electrical parts	<p>Exposed live (energized) electrical parts can be a source of shocks and/or sparks in the event of an electrical fault.</p>	<p>4</p>	<p>No exposed electrical parts (excluding patient monitoring leads) should be present in a chamber unless they have been certified as being intrinsically safe.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.19	Use of low-voltage, low-power equipment	<p>Low-voltage and low-power equipment is capable of producing sparks.</p> <p>Of even greater concern is the fact that it is capable of overheating under fault conditions.</p>		<p>All sensors and signaling, alarm, communications, and remote-control equipment used or intended for use within a chamber should meet the following requirements:</p> <p>4 a) Equipment should be isolated from AC power (also known as mains power) by either the power supply circuit design, opto-isolation, or other electronic isolation methods;</p> <p>3 b) All leads and cables not enclosed within conduits should be either part of intrinsically safe equipment or limited to less than 24 V_{DC} and 0.5 A under normal or fault conditions;</p> <p>4 c) The design of chamber speakers should be such that all electrical circuitry and wiring are enclosed, and their rating should not exceed 28 V_{rms} and 25 W; and</p> <p>3 d) Battery-operated devices should meet the requirements stipulated below under 1.6.21 on page.</p> <p>Alternatively, the following equipment configurations are considered acceptable:</p> <p>3 a) Equipment listed as intrinsically safe for use in Class 1, Division 1, Group B, locations;</p> <p>3 b) Equipment that is totally enclosed and constantly purged by means of an independently supplied, oxygen-compatible air source that automatically de-energizes if the air supply fails;</p> <p>3 c) Equipment that is hermetically sealed, filled with inert gas, positively pressurized, and fitted with an automatic de-energization device that trips if the initial pressure (i.e., when sealed) changes by more than 10%; or</p> <p>3 d) Equipment that has been approved for use by a competent authority and that has the written permission of the Safety Officer.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.20	Patient care devices	The risks associated with the use of electrical medical equipment in a chamber include current leakage, unvented batteries, off-gassing of batteries, sparking, heat-generation, and/or explosion or implosion due to inadequate venting.	<p>3</p> <p>3</p> <p>4</p> <p>4</p>	<p>In addition to the limitations noted above (i.e., a surface temperature of less than 85°C [185°F], an operating voltage of 24 V_{DC} or less, and adequate certification and/or testing for use within chamber environments), any patient-care devices used within a chamber should meet the following minimum requirements:</p> <p>a) Be designed and certified as safe for patient-care applications (e.g., per NFPA 99, Chapter 9);</p> <p>b) Electrical and mechanical integrity should be continuously monitored under the facility’s maintenance program;</p> <p>c) Devices that utilize oxygen should be designed so that oxygen cannot accumulate in electrical sections under any conditions;</p> <p>d) Devices have been successfully tested for proper performance over the chamber’s full operating pressure range.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.21	Use of portable battery-operated electrical or electronic equipment	<p>Any sources or users of electrical power can generate sparks and/or heat.</p> <p>In addition, batteries are a source of toxic and/or flammable gases under fault or heavy-load conditions.</p>	<p>4</p> <p>5</p> <p>5</p> <p>4</p> <p>4</p> <p>4</p>	<p>All such equipment – including permanently installed sensors; communications devices; and signaling, alarm, or remote-control equipment – should meet the following criteria:</p> <p>a) Batteries should be fully enclosed and secured within the equipment enclosure;</p> <p>b) Batteries should be compatible with the chamber’s maximum operating pressure and be of a sealed type that does not off-gas during normal use;</p> <p>c) Batteries should not be charged while they are inside the chamber;</p> <p>d) Batteries should not be changed while the equipment is located inside the chamber;</p> <p>e) Lithium-ion batteries should be excluded completely unless they are of the low-voltage type, used in implantable devices, or are monitored during use for any temperature increase that could result in overheating; and</p> <p>f) The equipment’s electrical rating should not exceed 12 V_{DC} and 48 W (28 V_{DC} and 25 W for communications).</p>
1.6.22	Chamber grounding	Inadequate grounding compromises the effective functioning of a chamber’s IPS as well as of any intrinsically safe equipment.	3	The resistance between the chamber and the ground point should not exceed 1 ohm.

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.23	Line isolation monitoring (LIM)	<p>Electrical leakage within a chamber can be a source of both localized hot spots and sparks.</p> <p>Adequate warning of fault situations is required to alert staff to the possibility of the power being shut off and of any consequential damage.</p> <p>All conductors coupled to a grounded power supply present the potential for sparking if contact is made with the chamber shell.</p> <p>High-voltage conductors (i.e., typically $\geq 110 V_{AC}$) represent a significant risk of electrocution.</p> <p>Life-support equipment requires a continuous power supply so as not to jeopardize medical support to patients.</p> <p>Electronic support devices are susceptible to detrimental levels of electrical noise.</p>	<p>3</p> <p>3</p> <p>3</p> <p>3</p>	<p>All AC electrical circuits inside a chamber should be supplied from an ungrounded IPS equipped with a LIM.</p> <p>The LIM should meet all of the following criteria:</p> <p>a) It should provide a continuous reading of the total hazard current;</p> <p>b) It should indicate a normal situation (with a green light) when the system is isolated from ground; and</p> <p>c) It should indicate a fault situation (with a red light and an audible alarm) when the leakage of current to ground exceeds the allowable threshold value (typically, 5 mA).</p> <p><i>Note: The trigger limit of 5 mA is set below the accepted “let go threshold” of 7 to 10 mA for AC current.</i></p> <p><i>However, it is only a predictive value. It represents current that would flow in the event of a low-impedance connection from either of the two live conductors to ground (not current that is actually flowing at that moment).</i></p>
1.6.24	Equipment outside of chamber	<p>A failure of critical electrical equipment outside the chamber in the event of flooding by a deluge system compromises the safety of chamber occupants.</p>	<p>4</p> <p>3</p> <p>4</p> <p>3</p>	<p>a) All equipment that must remain functional for the safe completion of a treatment after activation of a deluge system should be adequately waterproofed.</p> <p>b) Any conduits should be waterproof and, as applicable, be equipped with drains.</p> <p>c) All electrical circuits should be protected so that flooding by water does not constitute a further hazard.</p> <p>d) All electrical equipment should meet national regulations.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.6.25	Ground Fault Interrupter (GFI)	Electrical faults are a known source of ignition, equipment failure, and even shock.	3	<p>a) All external devices using electrical power, including patient-support equipment, should be supplied from a GFI, line isolation transformer system – providing an inductive link only, as well as indicator/warning lights.</p> <p>(Earth-leakage protection, achieved using a residual current device [RCD], a practice used in some countries, may fulfill these requirements.)</p> <p>3 b) A secondary circuit-sensing system should be used to sense single or balanced capacitive-resistive faults, as well as current leakage to ground.</p> <p>3 The sensor should be set to activate at a fault current of 30 mA within 300 ms or more stringent, as determined by the electrical system design engineer.</p> <p>3 c) The full load rating of the GFI should be twice the current rating of the equipment being used.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
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1.7 Communications & Monitoring

	<p>Warning: Ordinary communications equipment is not suitable for use within a chamber due to the potential for sparking from switches and arcing from microphones, both of which represent a distinct risk of fire.</p> <p>Communications and monitoring equipment are mandatory for the safe operation of a chamber; therefore such equipment must adhere to special provisions.</p> <p>Remark: “Electrical” requirements have been detailed under section 1.6 and are not repeated here.</p> <p>Compliance with the electrical equipment requirements remains mandatory in order to assure the required level of safety.</p> <p>Remark: The requirements for optional fire detection have been detailed under section 1.5.18.</p>			
1.7.1	External communications equipment	Electrical equipment – including power amplifiers, output transformers, and monitors – is generally capable of producing electrical discharge.	5	All such equipment should be installed for use only outside a chamber.
1.7.2	Internal communications equipment	The risks associated with internally installed transducers and communications equipment are detailed in section 1.6.19 Use of low-voltage, low-power equipment.	4	The requirements as detailed under Low-voltage, low-power equipment under section 1.6.19 should be complied with.
1.7.3	Communications between operator and occupant(s)	A breakdown in communications between the operator and the occupant(s) of a chamber can incur risks involving chamber operation, fire, occupant safety, and/or the outcomes of the medical therapy that is in process.	5 3 4	<p>a) A continuous, clearly audible communications link between the operator and all chamber locks should be in place whenever the chamber is in use.</p> <p>b) It is further recommended that the following be in place:</p> <ol style="list-style-type: none"> 1) A multichannel system, with discrete (closed-circuit) operator-attendant circuits, for discussion of sensitive patient issues; and 2) A sound-powered telephone or emergency communications system (e.g., surveillance microphones). <p>c) Communications channels between the locks and the control panel should be kept open at all times.</p>

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Ref.	Element	Risks	RL	Minimum Requirements
1.7.4	Individual patient communication systems	Individual patient microphones are contained within the oxygen delivery system and are therefore exposed to 100% oxygen – and thus may represent a direct source of ignition.	5	Where used, oxygen mask or hood microphones should be approved as intrinsically safe at the rated pressure and in 100% oxygen environments.
1.7.5	Oxygen (O ₂) monitoring	<p>Oxygen levels above 23.5% can increase flame propagation exponentially and are classified as highly dangerous.</p> <p>If diluent gases are introduced, oxygen levels below the safe partial pressure for a specific chamber pressure, can result in a hypoxic environment.</p> <p>Chambers that are large (i.e. diameter greater than 1.8 m [6 ft], a treatment lock longer than 3 m [10 ft] or designed for more than six occupants) or that are designed with restricted interior air flow (i.e., limiting the immediate dilution of gases) may retard the ability of oxygen analyzers to indicate the actual average oxygen levels present in the environment.</p>	5 3 5	<p>a) Oxygen levels should be monitored at all times.</p> <p>Visual and audible alarms should indicate oxygen concentrations above 23.5% or below 19.5%.</p> <p>b) Monitoring should preferably occur at two or more treatment lock locations, especially in larger chambers, with one sample point located near the ventilation outlet or the chamber’s exhaust point.</p> <p>c) Chambers should not be operated with interior oxygen levels above the safe limit of 23.5%.</p>
<p><i>Comment: Treatments associated with commercial diving operations may require oxygen percentages below 19.5%. Since such treatments will be performed only under the direct supervision of a suitably qualified medical practitioner or life-support supervisor, the determination of allowable minimum levels in such cases is left to the discretion of the supervising individual and accepted and safe diving practices.</i></p>				

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Ref.	Element	Risks	RL	Minimum Requirements
1.7.6	Carbon dioxide (CO ₂) monitoring	<p>CO₂ levels can build up during a long treatment involving little or no ventilation.</p> <p>High CO₂ levels are dangerous and can potentiate oxygen toxicity.</p> <p>CO₂ intoxication can be insidious and thus difficult to discern.</p>	3	<p>If ventilation is not (or cannot be) used, CO₂ levels within the chamber should be monitored continuously.</p> <p>Visible and audible alarms should indicate CO₂ concentrations above the safe surface equivalent value (SEV) relative to treatment pressure (depth).</p> <p><i>The SEV represents the equivalent of the CO₂ level at pressure to the level at the surface:</i> $SEV = CO_2 \times \text{pressure in ATA}$</p> <p><i>E.g., an allowable CO₂ exposure level of 0.5% (5,000 ppm_v) implies a maximum allowable level (SEV) at 26 psi (2.8 ATA) of $5,000 \div 2.8 = 1,786 \text{ ppm}_v$, as measured by the analyser at the chamber control panel.</i></p>
1.7.7	Combustible gas monitoring	Where flammable gases are used within a chamber, any leak or compromised gas-discharge circuit will create an immediate explosion hazard.	5	<p>Flammable gases should not to be used.</p> <p>Where the Medical Director decides to override this safety requirement, such a decision should be discussed with the Safety Officer, and special precautions taken to limit the possible explosion hazards.</p> <p>One of these precautions should include continuous monitoring for the combustible gas(es), with audible and visual alarms set at 10% lower explosion limit (LEL) for the specified gas.</p>
1.7.8	Chamber air supply monitoring	<p>Two sources of contamination exist, viz. those present in ambient air and those added by gas-compression equipment.</p> <p>Where oil-lubricated compressors are used or where compressor intakes are positioned in areas that could be polluted by motor vehicle exhausts, toxic, oil-vapour or other hydrocarbon contaminants could be rapidly introduced.</p> <p>Toxic gases such as carbon monoxide (CO) will compromise the health of the occupants.</p>	<p>4</p> <p>4</p> <p>3</p>	<p>a) Compressed air plant should be fitted with suitable air-treatment packages capable of producing air safe for breathing purposes, as well as compatibility with oxygen, referred to as oxygen compatible air (OCA).</p> <p>b) Air should be sampled for possible contaminants (CO₂, CO, moisture, oil and particulates) at least every six months.</p> <p>c) Automatic safeguards should be considered where volatized HCs and CO could be present, especially where oil-lubricated compressors are used (ref. also section 1.4.8).</p>

1. Construction and Equipment

Ref.	Element	Risks	RL	Minimum Requirements
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1.8 Other Equipment and Fixtures

1.8.1	Permanently installed furniture	Ungrounded permanent furniture and other fixtures electrically isolate occupants, thus enhancing the buildup of static electricity and reducing the effective functioning of a chamber's electrical protection and safety systems.	3	All permanently installed furniture should be grounded.
1.8.2	Exhaust systems	Three risks may be associated with inadequate exhaust systems, viz. noise, resistance to flow, and increased oxygen concentration at the outlet.	3	<ul style="list-style-type: none"> a) Exhaust should be piped outside the building, to a location that is clear of nearby hazards and where re-entry of exhaust gases back into the building is unlikely. <li style="margin-top: 10px;">3 b) Exhaust outlets should be located away from falling rain and other debris, and be fitted with a mesh or suitable material to prevent animals from entering and/or nesting, potentially causing a blockage or resistance to flow. <li style="margin-top: 10px;">3 c) Exhaust exit locations should be clearly identified with signage that prohibits smoking or any open flames in the immediate vicinity.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.1 Procedural Requirements

	<p><i><u>Explanation:</u> The determination of suitable patient preparation, together with administration and records are fundamentally important aspects affecting both safety and efficacy of hyperbaric treatments, as well as the effective functioning of the hyperbaric facility.</i></p> <p><i>The UHMS Multiplace Hyperbaric Chamber Safety Guidelines, specifically chapters VIII and IX, contain details of medical considerations required during assessment, orientation and treatment modality, together with administration and records.</i></p> <p><i>The majority of these sections are not included within the scope of the risk assessment process, as they are assumed to form part of the training, function and discretion of the responsible medical practitioner.</i></p>			
2.1.1	Standards	Minimum standards are required to ensure effective and safe treatment facilities.	4	<ul style="list-style-type: none"> a) Hyperbaric services that meet the needs of patients, as determined by the nature of the health care facility or practitioner, should either be available at all times, or within an acceptable notification period. 4 b) Facilities should be organised, integrated, staffed and directed commensurate with the scope of services offered. 4 c) The scope of services (medical and technical) should be clearly defined. This is essential to allow for proper transfer and referral of patients. 4 d) Patient support capabilities (IV infusion, ventilator support, vital signs) should be appropriate for the level of service provided.
2.1.2	Recognition of hazards	Until all risks associated with the hyperbaric facility have been identified and mitigated, the facility may remain at risk.	5	<ul style="list-style-type: none"> a) The recognition of the multitude of hazards associated with hyperbaric facilities is a complex task. This document serves to identify the known risks and is intended as a guide to the appointed Safety Officer to identify and fully address all risks prior to commencement of operation. 5 b) Attention to detail (as should be stipulated within the standard operating procedures of the facility) by all administrative and maintenance personnel responsible for the functioning of the facility, will mitigate the hazards associated with the use thereof

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.1.3	Personnel	The administration of hyperbaric oxygen therapy must be done by competent and thoroughly trained staff in order to ensure patients' safety, the efficacy of treatments, and the responsible practice of medicine.	4 4 4 4 4	<p>a) Staff should be appointed in writing, provided with clear responsibilities and delegated with the appropriate authority. All units should employ the services of at least the following staff:</p> <p>b) Medical Director - a registered and suitably qualified, hyperbaric medical practitioner, responsible for all medical activities and for the direction, quality, safety and service provided by the facility. This person, or qualified designate, should be available throughout all treatments.</p> <p>c) Safety Officer - an appropriately qualified and competent person who is responsible for of all equipment, operations and maintenance within the facility; and who is authorised to control the access of equipment and supplies to the chamber. This person, who may also be a supervisor or chamber operator, should be involved in all aspects of planning, regulations and use of the facility.</p> <p>d) Technical Supervisor/Technician - a trained and certified hyperbaric medical technologist (who may be a nurse, diving medical technician, or other suitably trained person), who is required, depending on the scope of services, to be delegated with the supervision of hyperbaric personnel, operation of the equipment, maintenance, training and the provision of hyperbaric therapy.</p> <p>e) Support personnel - these include registered nurses, emergency service personnel and paramedics, who are trained and certified as competent to attend to patients both inside and outside of the chamber.</p>
2.1.4	Personnel health & safety	<p>Staff working within a hyperbaric unit may be subjected to specific occupational hazards including:</p> <p>a) Adverse reactions to disinfectants & cleaning solutions;</p>	4	<p>a) The facility should maintain a long-term medical surveillance program with active monitoring of staff health and safety issues.</p> <p>Such a program should include entry, periodic & exit medical examinations.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
	Personnel health & safety (cont.)	<p>b) Risk of infection from patient-borne diseases; and</p> <p>c) Physical injuries (especially as a result of patient handling efforts).</p>	<p>4</p> <p>4</p>	<p>b) Any form of adverse reactions, conditions or illnesses should be investigated to determine whether the causes are occupationally-related or not.</p> <p>c) Occupational health issues require specific reporting, monitoring and follow-up to comply with employment regulations.</p> <p>It is recommended that this service be outsourced to an independent occupational health provider.</p>
2.1.5	Responsibility	<p>The safety of a hyperbaric facility is affected by the conditions and practices in and around the unit, as well as in the health-care facility where it is located.</p> <p>If responsibility for those conditions and practices is not clearly assigned, it can put the safety of the chamber at risk.</p>	<p>4</p> <p>4</p> <p>3</p> <p>3</p>	<p>a) The ultimate responsibility for the care and safety of patients and personnel lies with the health care facility's board.</p> <p>This board should thus ensure that safety, rules, practices and conduct throughout the facility are effectively and formally delegated to competent and responsible people.</p> <p>b) The hyperbaric facility Medical Director is responsible for the daily activities surrounding the facility.</p> <p>All personnel delegated with the responsibility of operating, administering, inspecting and maintaining the facility and all the associated equipment should be under the direct control of the appointed Medical Director.</p> <p>c) The Safety Officer should be responsible to both the Medical Director, as well as to the health care facility's safety committee regarding all equipment and related safety matters.</p> <p>However, the Medical Director should remain ultimately responsible as the "user" as defined under occupational health and safety regulations.</p> <p>d) In all cases, the medical staff should adopt and adhere to the professional regulations pertaining to the use of facilities located within formal health care facilities.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.1.6	Policies	Policies that fail to integrate and account for the sometimes-conflicting requirements detailed in national, regional, and municipal statutes and regulations and in international guidelines and industry-specific equipment instructions can seriously compromise operational safety (e.g., there can be variation in matters such as the allowable oil-vapor content in compressed air or the allowable voltage in a confined space).	3	An integrated set of policies – mandating compliance with all applicable national, regional, and municipal statutes and regulations, especially those regarding the use of equipment – should be established and enforced by suitably competent and experienced personnel.
2.1.7	Operating procedures	Inadequate, unproven and non-formal operating and safety procedures can present a serious hazard to the safe operation of the hyperbaric facility. This is applicable to both normal operations as well as to emergency procedures.	3	Internationally accepted, qualified and well-proven procedures should be established, implemented and continuously monitored.
2.1.8	Implementation & compliance	Procedures that have not been correctly implemented nor adhered to, and staff that are not trained to understand and follow such procedures, will result in mistakes and oversights that will endanger the safety of both patients and staff.	5 3	a) The Medical Director is responsible for ensuring that staff receive the appropriate training (ref. section 2.10), adhere to operating and safety procedures, and are competent to fulfil their respective responsibilities effectively. b) The Medical Director should ensure that periodic audits of the effective functioning of the operating and safety management systems are conducted.
2.1.9	Regular operator inspections	If chamber operators fail to conduct regular pre- and post-treatment inspections of the chamber, risky situations could arise (e.g., patients taking hazardous items into the chamber, etc.).	4	A set of comprehensive pre- and post-treatment checklists should be established as part of the treatment log. This will ensure that the operator is reminded to perform the necessary safety, cleaning, and system checks before and after each and every treatment.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.1.10	Patient transport and referral procedures	A failure to establish procedures for when and how a patient is transferred elsewhere could place the patient at risk and could open a facility to liability.	4	<p>Procedures should be established regarding when and how to transport emergency cases to or from the healthcare facility, if the hyperbaric unit is not attached to a full-service medical facility.</p> <p>Self-standing or independent hyperbaric facilities should not undertake stabilization or extended care of emergency cases.</p>
2.1.11	Rules & regulations	<p>A lack of adequate training, discipline, contingency planning, or adherence to procedures represents a risk to the facility, patients and staff.</p> <p>Lack of sufficient responsible and trained staff also represents a risk.</p>	<p>4</p> <p>5</p> <p>5</p> <p>5</p> <p>4</p> <p>5</p> <p>4</p>	<p>a) The Medical Director and Safety Officer should establish clear rules and regulations for the operation of the facility, including the use of emergency equipment.</p> <p>b) All staff should be thoroughly trained in the implementation of these rules and regulations.</p> <p>Such training should include regular follow-up sessions, hands-on training, and regular emergency and fire drills.</p> <p>c) Treatments should be performed only under the direct supervision of a medical doctor, with appropriate HBO training and experience.</p> <p>d) The operator should remain in attendance throughout every treatment, irrespective of any emergency that may occur.</p> <p>e) The Medical Director and Safety Officer should ensure that discipline is maintained at all times.</p> <p>They are also responsible for contingency planning and training.</p> <p>f) All staff should be thoroughly trained and experienced in the use of emergency equipment.</p> <p>g) The Medical Director should establish minimum staff qualifications, experience levels staffing levels based on the nature and size of the HBO facility, as well as the type of therapy normally provided.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
	Training (cont.)		3	<p>c) The Safety Officer, in conjunction with the Medical Director, should identify the requirements for refresher training, especially for staff who are not engaged in providing treatments on a regular basis.</p> <p>The types of such training include the following:</p> <ol style="list-style-type: none"> 1) Formal qualifications, ref. a) above: Unless specified otherwise by a governing body, refresher training should occur at least every two years. 2) Facility-specific training, including operational and emergency procedures: The frequency of such refresher training should be based on the frequency with which the staff member performs treatments and the number of drills held within a 12-month period. Staff members should not be allowed to participate in treatment activities unless they have either performed treatments or received refresher training within the previous 12 months. In any case, refresher training should be conducted at least every two years.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.2 General Requirements

2.2.1	Direct heat sources	The presence of open flames, smoking materials and/or heated objects represents a serious hazard in the operating environment.	5	Any object that could be a source of heat or UV radiation; that could trigger the chamber's fire detection system (if it has one); or that could degrade acrylic viewports should be specifically banned from hyperbaric facilities – either within the chamber or in its immediate outside vicinity.
2.2.2	Flammable gases & liquids	Flammable gases and liquids, especially with higher elevated oxygen levels, represent a serious risk of fire, even after the completion of treatments.	5 4	<p>a) All flammable gases and liquids, including those contained in cigarette lighters and chemical hand warmers, are forbidden inside the chamber, as well as near the intake to the compressor(s).</p> <p>b) Alcohol-based pharmaceuticals should be permitted only if they are medically necessary; have been authorized by the health-care professional treating that specific patient; and have the specific consent of the facility's Safety Officer.</p> <p>The quantities of such products should be limited to an extent such that only an insignificant amount of flammable vapor could be released into the chamber environment.</p> <p>In addition, oxygen monitoring procedures should be strictly followed, and all sources of electrostatic spark discharge should be eliminated.</p>
2.2.3	Personnel	Overcrowding and the presence of superfluous personnel represent a risk to safe operations, as well as to the management of emergency situations.	3	<p>Non-essential personnel should be kept out of the treatment areas.</p> <p>People accompanying patients should be restricted to formal waiting areas.</p>
2.2.4	Textiles & toiletries	<p>Certain fabrics represent a serious risk in hyperbaric environments, especially in the event of a fire.</p> <p>For example, synthetic materials tend to retain oxygen in their closed-cell construction, creating a concentrated source of oxygen, and nylon undergarments can</p>	3 3	<p>a) Procedures should be in place to ensure that patients wear only approved garments fabricated of 100% cotton or blend of cotton and polyester.</p> <p>Silk, wool and synthetic materials should be specifically banned.</p> <p>b) Dedicated garments, supplied by the facility to patients before treatments, are strongly recommended.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
	Textiles & toiletries (cont.)	<p>burn into the skin at high temperatures.</p> <p>Loose-fitting garments can incur the following risks:</p> <p>a) They can make it difficult to determine whether patients are carrying hazardous items with them;</p> <p>b) They can compromise the wearer's safety in the event of a fire because they may retain trapped gas, expose skin, and/or interfere with a deluge system's operation; and/or</p> <p>c) They can catch on equipment or protuberances.</p> <p>The use of fabrics such as blankets, sheets, or drapes in a chamber represents additional fuel in the event of a fire.</p> <p>Certain personal toiletries and cosmetics represent a risk of fire.</p> <p>Percussion sparks caused by shoes containing ferrous nails are further increased where aluminium deck-plates are installed.</p>	<p>4</p> <p>3</p> <p>3</p> <p>3</p> <p>3</p> <p>4</p> <p>4</p>	<p>c) In addition, where patients are contaminated with oils or grease (such as accident victims), they should be cleaned before donning facility treatment garments.</p> <p>d) Wherever possible, all other fabrics should be treated with flame reducing compounds or be inherently flame-resistant. It is important to note that flame-retardant compounds often require regular reapplication, especially after washing. The instructions of the compound's manufacturer should be closely followed.</p> <p>e) Although most medical dressings do not pose a significant risk, substances such as petroleum jelly (Vaseline) and hook and loop fasteners (Velcro) should be avoided. The Medical Director should make any safety decisions in this regard.</p> <p>f) Garments should cover as much of the patient's skin as possible.</p> <p>g) Garments should either be supplied without pockets or pockets should be sewn up, to reduce the risk of patients bringing hazardous items into the chamber.</p> <p>h) Flammable hair sprays, hair oils, skin oils and cosmetics should be banned for all operating personnel as well as patients.</p> <p>i) As a general rule, patients should be prevented from wearing their own shoes in the chamber. Where this rule must be waived, the staff should ensure that no ferrous bearing items are present in their shoes, which may create sparks on aluminium deck plates.</p>
2.2.5	Porous Materials	Materials such as wood or clothing may retain oxygen for a significant period after treatment.	3	Porous or closed-cell materials should be excluded (or at least controlled) from being taken into the chamber.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.3 Emergency Procedures

2.3.1	Procedures for emergency situations	<p>It is often not possible for operating and attending staff to react effectively in an emergency unless they have received adequate training and support.</p> <p>Emergencies may be operational or technical in nature, or may involve medical issues for patients and staff.</p> <p>Medical issues in patients are dealt with in 2.3.2 (below) and for staff in 2.3.3 (below).</p>	5	<p>It is imperative that every hyperbaric unit establish and document emergency procedures to ensure the safe completion of treatments and the safe evacuation of patients and staff in the event of an emergency, as well as the effective handling of any potential emergency situation.</p> <p>The following are among the emergency situations that should be covered:</p> <ul style="list-style-type: none"> • loss of primary oxygen and/or air supply • loss of back-up oxygen and/or air supply • contamination of oxygen or air supply • rapid increase or decrease in chamber pressure • fire inside or outside the chamber • loss of power • failure of any chamber systems (communications, controls) • activation of fire deluge system (either accidental or intentional)
2.3.2	Procedures for patient medical emergencies	<p>Medical emergencies must be dealt with promptly to avoid fatalities and to prevent disability resulting from injuries or diseases.</p>	5	<p>It is imperative that each hyperbaric unit establish and document emergency procedures to ensure that patient medical emergencies can be managed appropriately.</p> <p>The following are among the situations that should be covered:</p> <ul style="list-style-type: none"> • Oxygen toxicity • Arrhythmias, cardiac arrest (& defibrillation) • Pneumothorax • Barotrauma (middle ears, sinuses, teeth, lungs, intestinal) • Arterial gas embolism • Respiratory distress / bronchospasm • Suspected hypoglycaemia • Vomiting • Loss of consciousness • Claustrophobia

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.3.3	Procedures for medical emergencies in staff	<p>Medical emergencies in staff should be dealt with in a standardized manner to prevent illness or injury that could result in disability or render the staff member unable to manage occupants of the chamber.</p> <p>Occupational injuries and diseases carry an additional legal risk and emergency procedures should take into account any specific legal requirements that may apply</p>	5	<p>It is imperative that each hyperbaric unit establish and document emergency procedures to ensure that staff medical emergencies can be managed appropriately.</p> <p>Some “patient-procedures” will also apply to staff, but dedicated procedures should be available for:</p> <ul style="list-style-type: none"> • Sharps injury or fluid exposure • Occupational injury (e.g. barotrauma) or occupational disease (e.g. hearing loss or skin conditions) • DCI

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.4 Equipment

2.4.1	Approved equipment	The use of noncompliant or unapproved equipment, instruments, or devices represents a risk of explosion, implosion, and/or fire.	4 4	<p>a) Only equipment that is specifically compliant with the requirements of this document, or that has been specifically approved for use within hyperbaric chambers, should be used.</p> <p>b) All other equipment is expressly prohibited from being taken into the chamber. This includes any high-energy devices, photographic flashes, lasers, tablets and cellular telephones.</p>
2.4.2	Defective equipment	Defective equipment can compromise safety and hamper emergency responders.	5	Defective equipment, or equipment suspected of being defective, should be withdrawn from use and repaired to the satisfaction of the Safety Officer prior to being returned to the chamber.
2.4.3	Flammable items	Flammable items and substances include the obvious possibilities, as well as less obvious items like paper and lubricants, all of which represent a risk of fire.	4	<p>a) Flammable items should be kept to an absolute minimum inside the hyperbaric chamber.</p> <p>b) Newspaper should be expressly prohibited, due to the volatile inks used by some papers.</p>
2.4.4	Temperature ratings	Equipment with unsuitable temperature ratings can cause a fire or explosion.	5	<p>All equipment intended for use in a chamber should strictly follow the chamber's temperature rating requirements.</p> <p>This matter requires particular vigilance by staff.</p>
2.4.5	Oxygen equipment compatibility	Many items if ignited within a pressurised, oxygen-enriched atmosphere are not self-extinguishing.	4 3 3	<p>a) Only approved, dedicated oxygen containers, control mechanisms, interconnecting hoses and fittings, valve-seat materials and lubricants should be used.</p> <p>b) International guides for determining the suitability of materials for oxygen compatibility should be followed.</p> <p>c) Static conditions and impact conditions are both applicable. ASTM and NFPA guidelines for design using oxygen-compatible materials should be followed.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.4.6	Oxygen cleaning procedures	Contamination of oxygen equipment presents risk of fire or explosion.	3	Oxygen equipment, including fittings, connections, gas handling equipment, etc. should be oxygen cleaned prior to use. Oxygen cleaning requires special considerations and only approved procedures should be used.
2.4.7	Oxygen lubricants	HC lubricants are a known source of fuel in an oxygen-enriched environment.	4	Only oxygen compatible lubricants should be used inside the hyperbaric chamber.
<p><i>Caution: Certain sealed equipment, for example Tycos™ pressure bags, contains hydrocarbon-based lubricants that are unacceptable.</i></p> <p><i>Special oxygen compatible lubricated units are available from Tycos™.</i></p>				
2.4.8	Light metals	Light metals such as cerium, magnesium and magnesium alloys are all capable of burning in air.	5	All combustible light metals are prohibited from being used within a hyperbaric chamber.
2.4.9	Radiation exposure	<p>X-rays or gamma radiation can degrade acrylic windows.</p> <p>This risk is especially applicable if the source of radiation is located outside the chamber and the radiography is delivered through the viewport.</p> <p>Direct sunlight is also a known source of harmful UV and infrared radiation capable of degrading acrylic windows.</p>	<p>4</p> <p>3</p>	<p>a) If acrylic windows will be exposed to any form of high-energy radiation, facility owners and managers should be aware that the service life of the window will be drastically reduced.</p> <p>The maximum allowed absorbed dose is 40 kilo gray (kGy) (4 mega rad [Mrad]).</p> <p>Exposure to X-rays or gamma radiation reduces window service life to three years.</p> <p>b) Exposure to harmful UV or infrared radiation (e.g., from direct sunlight) reduces the service life of acrylic windows.</p> <p>In such cases, ASME PVHO-2 requires strict adherence to a maximum service life of 10 years.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.5.4	Flammable gases	Flammable gases represent a severe risk of fire.	4	No flammable gases should be stored in or near the hyperbaric facility, or near any compressor intake(s).
2.5.5	Stored gases	<p>Large quantities of stored gas, especially oxygen, elevate the risk in the event of a fire, especially if the storage containers are not regularly inspected for leaks, etc.</p> <p>Pressurized containers also represent a risk of explosion.</p>	3 3	<p>a) The amount of oxygen stored in or around the hyperbaric facility should be kept to the minimum required to complete treatments, and to deal with emergency situations.</p> <p>b) Pressurised containers should only be taken into the hyperbaric chamber where they are approved for use.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.6 Maintenance

2.6.1	Regular testing & calibration of equipment	Inadequate maintenance of oxygen-handling equipment, chamber controls, and safety equipment can result in equipment failure, representing risks for both operators and patients.	3 3	a) The Safety Officer should be responsible for ensuring that all equipment is regularly checked and serviced. b) Pressure relief valves, gauges and analysers require regular calibration.
2.6.2	Labelling of gas outlets	Inadequate labeling of oxygen-system components, especially outlets, risks their not being identified during emergencies.	3	All essential controls on an oxygen system, especially gas outlets, should be clearly labeled. It is also imperative that the gases delivered at every labeled outlet are checked prior to their first use (by reviewing the attached certificate[s] of analysis or, preferably, by online gas analysis).
2.6.3	Replacement parts	The use of non-specified spares and replacement parts may result in premature equipment failure.	3	The Safety Officer should be responsible for ensuring that only manufacturer-authorized components are used both during initial installation and during subsequent maintenance of all equipment.
2.6.4	Authorised work	All installation, repair and modification work to hyperbaric chambers and their associated equipment directly affects the safe function of the facility.	3	The Safety Officer should ensure that only competent personnel perform repair and maintenance work according to the provisions of both legal requirements and equipment manufacturer's manuals.
2.6.5	Maintenance logs	A lack of operating and/or maintenance logs precludes adequate control of maintenance procedures, potentially resulting in premature equipment failure.	2	The Safety Officer should sign off on all maintenance procedures and ensure that logs of all operating and maintenance procedures are maintained.
2.6.6	Cleaning of filters	Blocked or partially blocked filters reduce efficiency of chamber operation, provide a risk where rapid decompression may be required, and may introduce dirt and contaminants should filters fail as a result of excessive loading.	3 3 3	a) The chamber gas supply inlet filters should be cleaned or changed at least annually. b) Inlet filters for regulators, flow controls and the exhaust system require annual maintenance. c) Manufacturers' recommendations should be adhered to at all times.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.6.7	System maintenance	<p>Inadequate and incomplete maintenance could result in</p> <ol style="list-style-type: none"> 1) deterioration of systems from optimally safe readiness; and/or 2) failure of systems affecting safety during operation. 	<p>3</p> <p>3</p>	<p>Adequate and effective system maintenance requires that several elements be addressed:</p> <ol style="list-style-type: none"> a) Competent personnel who have been appointed by the Safety Officer should evaluate initial installation, repair, and modification of equipment. <p>This evaluation should include testing under pressure.</p> b) The Safety Officer should ensure that a comprehensive preventative maintenance system is in place, which should include: <ol style="list-style-type: none"> 1) periodic testing of all safety related equipment (e.g. gauges, valves, meters, deluge systems, warning systems, etc.); 2) checking of oxygen piping systems for leaks; 3) checking that gas flows remain unobstructed; 4) ensuring continued operation of all automatic drains (where no condensate is discharged then the drain valves should be checked for blockages and the filter elements checked to ensure that these are not saturated). 5) replacement of filters, lubricants and coolants; 6) checking of fluid levels; 7) adjustment of regulators, sensors, safety valves and switches; 8) correct and effective activation of safety systems (i.e. electrical alarms, emergency power, back-up gas supplies); 9) analysis of gases; 10) monitoring of viewports, pressure boundaries, calibration and statutory testing status; and 11) updating logs of all periodic tests, which should be scrutinised regularly.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
	System maintenance (cont.)		3	<p>c) A documented corrective maintenance system should be in place.</p> <p>This should include the full cause-and-effect recording of all system failures and break-downs; logging of corrective actions; placing of “holds” on further manned pressurisation excursions until resolved and approved by the Safety Officer; and regular audits by the Safety Officer.</p>
			3	<p>d) A suitable, dedicated maintenance area, equipped with dedicated tools and instruments, is required to enable personnel to affect repairs, replacement and cleaning with minimum “downtime”.</p>
2.6.8	System cleaning procedures	<p>Ineffective or incomplete cleaning of hyperbaric piping and gas storage systems can introduce dangerous substances into the systems, posing a risk of fire or toxic contamination.</p> <p>A failure to thoroughly clean chambers and their associated equipment on a daily basis can result in the spread of transmissible diseases.</p>	3	<p>a) After initial installation, repairs or modifications of any gas supply or control systems, a cleanliness certificate should be issued that meets the satisfaction of the Safety Officer.</p>
			3	<p>b) The placement of suitable filters at positions such as the oxygen or air inlet should be considered as appropriate.</p>
			3	<p>c) Suitable cleaning procedures should be documented and should be certified as effective by the Safety Officer prior to being implemented.</p> <p>These procedures should preferably include objective inspection and testing instructions.</p>
			3	<p>d) Suitable, noncorrosive antiseptics and detergents should be used to clean all surfaces at the end of every treatment day.</p>
			4	<p>e) Caution is required in cleaning certain components (e.g., viewports, fire-resistant materials) to avoid degradation of the material or a reduction in its fire-resistant properties.</p>
			3	<p>f) Safe and comprehensive protocols should be established regarding issues such as protective clothing, disposal of cleaning containers, disposal or cleaning of contaminated linens, inspection of chambers after they have been cleaned, and adequate ventilation both during cleaning and prior to treatments.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
	<p><i>Warning: Trichloroethylene is not recommended as a cleaning compound in hyperbaric chambers. Apart from personnel hazards, the fluid reacts with CO₂ absorbent chemicals forming a toxic, volatile and even explosive compound.</i></p>			
2.6.9	Approved lubricants or consumable materials	Many common and accepted lubricants and consumable materials are not safe for use within a hyperbaric environment, especially in the presence of high concentrations of oxygen.	4	<p>a) The criteria by which materials are judged to be safe for use in a hyperbaric environment should include the following:</p> <ul style="list-style-type: none"> • Suitably pressure-rated and oxygen-compatible; • Nontoxic; • Nonreactive with system elastomers and other similar materials; • Noncorrosive; and • Effective and easy to apply or use. <p>b) Materials should be clearly identified for their intended use and should be packaged to keep out contaminants.</p> <p>c) Lubricants should be used sparingly and should not be used to correct equipment flaws (e.g., on nonsealing joining surfaces or to compensate for a poor fit).</p> <p>All excess lubricants should be removed prior to the use of the equipment.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.7 Electrical Safeguards

2.7.1	Testing	Any electrical faults or failures of a chamber's protective equipment presents considerable risk to the safety of the operating environment.	4	All electrical circuits, ground fault interrupters (GFIs), and line insulation monitors (LIMs) should be tested before each treatment session, to assure that they are functioning normally and that no live conductors are grounded.
2.7.2	De-energization of equipment	A failure to de-energize electrical equipment during a fire, especially in facilities with a sprinkler or deluge system, can be exceedingly dangerous, due to the risk of electrical shock and even death if water comes in contact with an electrical fire.	4	Any electrical equipment either in or attached to the chamber that is not life-critical should be de-energized prior to the activation of a sprinkler or deluge system (unless it is adequately waterproofed).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.8 Electrostatic and General Safeguards

2.8.1	Electrostatic sparks	<p>Electrostatic discharge may present a potential ignition source, may disrupt electrical monitoring equipment and is a source of discomfort for chamber patients.</p> <p>In addition to the potential sources of static generation from equipment or materials, a patient moving normally inside a (dry) chamber may build a static charge.</p>	<p>3</p> <p>3</p>	<p>a) The elimination of static charges requires the vigilance of all operating personnel, control of materials purchased, maintenance, periodic inspection and testing, and the constant awareness of static sources.</p> <p>b) Patients should be grounded to a metallic non-moving, permanently grounded part of the chamber using a suitable grounding device, prior to the door being closed.</p>
2.8.2	Conductive flooring	In dry locations, unsuitable, ungrounded flooring materials may build static charges.	2	Conductive flooring around the chamber, as pertaining to anaesthetizing locations within health care facilities, should apply where needed.
2.8.3	Fixtures and internally located, non-fixed equipment	<p>Inadequate grounding, loose conductive fixtures and materials could hinder effective grounding inside the chamber.</p> <p>Impact, high temperature sparking may occur where ferrous containing parts and aluminium surfaces are used in areas of with high-loading.</p>	<p>3</p> <p>3</p> <p>4</p> <p>3</p> <p>3</p>	<p>a) Periodic inspection of the integrity of joints, grounding and insulation by loose foreign materials should be conducted.</p> <p>b) Movement of fixtures should be avoided during treatments.</p> <p>c) Metals exhibiting impact-sparking potential should not be used in high loading areas.</p> <p>d) Accessories such as sheets, plastic covers, rubber accessories, etc. should be selected on the basis of reduced conductivity or antistatic properties</p> <p>e) Casters and bearings inside the chamber should be regularly inspected, cleaned and lubricated using oxygen-compatible, conductive lubricants.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.9 Housekeeping

2.9.1	Tidiness	Cluttered and untidy facilities present a safety hazard in terms of operational control, especially during emergency situations.	3	The Medical Director should ensure that operating areas are kept free of unnecessary equipment, that non-essential equipment is stowed away, and that essential equipment is at hand.
2.9.2	Cleanliness	A build-up of flammable materials, such as grease, dirt, lint and dust, presents a fire hazard.	3	a) It is essential that the hyperbaric chamber be kept meticulously free of all greases, lint, dirt, dust and unwanted materials.
			3	b) The person tasked with this daily function should be thoroughly briefed as to the dangers to occupants under normal operating conditions.
2.9.3	Diseases & contamination	The lack of, or inadequate, daily cleaning of the chamber and equipment may cause transmission of diseases and spread of contamination.	3	a) A suitable, non-corrosive, antiseptic (e.g. quaternary ammonia-based) and synthetic (e.g. non-soap detergent) should be used to clean all surfaces following each treatment day.
			3	b) Due caution is required in cleaning certain hyperbaric components, viz. fire-treated bedding and mattresses, to avoid degradation or a reduction in fire-resistant properties.
			3	c) Safe and effective protocols should address issues such as protective clothing, disposal of cleaning containers, disposal or cleaning of contaminated linen, inspection of chamber after cleaning, and adequate ventilation during cleaning and prior to treatments.
2.9.4	Acrylic cleaning procedures	The visibility and life span of acrylic materials can be reduced by: <ul style="list-style-type: none"> • Abrasion - reducing visibility; • Surface damage - reducing life span; and • Degradation due to chemical incompatibility - reducing visibility and life span. 	4	a) Antiseptic and cleaning compounds should be specifically certified as being suitable for acrylic viewports.
			4	b) Due caution is required in cleaning acrylic components to avoid mechanical damage.
			4	c) A soft, lint-free cloth should be used to clean the acrylic window.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.9.5	Standby conditions	During extended periods of down-time (i.e. the chamber is not being used), there may be less attention to housekeeping, with the corresponding danger of non-compliance with facility safety procedures.	3 3 3	a) Only properly trained personnel should be allowed to clean the facility. b) The entry of unauthorised personnel into the facility should be prevented. c) The facility should preferably be kept secured (locked) at all times.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.10 Medical Staff Training, Qualifications, Registration and Affiliations

	<p><i>Note: All hyperbaric health care providers should have the necessary and appropriate training and skills to deliver hyperbaric therapy in a safe, appropriate and ethical manner.</i></p> <p><i>Multiplace chamber operators may be persons who are not licensed medical personnel when non-critical patients are being treated.</i></p> <p><i>Different regulatory requirements might apply in specific areas.</i></p> <p><i>Medical practitioners and licensed medical personnel should always be involved in patient treatment and a medical practitioner should be immediately available during patient treatments.</i></p> <p><i>Increased legal liability risks exist where chamber staff are not professionally registered (i.e. certified), as is appropriate.</i></p>			
2.10.1	HBO medical practitioner	<p>The ability to administer and monitor hyperbaric medical treatments requires specific knowledge, training and experience.</p> <p>Patients may present with a range of responses and side effects.</p> <p>Numerous medical complications and situations may arise.</p> <p>The sealed pressure vessel housing the patients restricts the practitioner from immediate hands-on management of the patient.</p>	4	<p>The HBO medical practitioner should hold the following minimum qualifications and registration:</p> <ul style="list-style-type: none"> • Registration with a State or applicable board as a medical practitioner. • Hyperbaric medicine training, as endorsed by the national hyperbaric medical association (see also to 2.10.5 below). • Current BLS training (ACLS training is recommended). • Be declared medically fit to enter the chamber while under pressure.
2.10.2	Hyperbaric nurse	<p>Nurses are also employed to administer and monitor hyperbaric medical treatments.</p> <p>Nurses require specific knowledge, training and experience.</p> <p>Patients may present with a range of responses and side effects.</p> <p>Numerous medical complications and situations may also arise.</p>	4	<p>The hyperbaric nurse should hold the following minimum qualifications and registration:</p> <ul style="list-style-type: none"> • Registration/licensure as a nurse. • Hyperbaric nursing training, as endorsed by the national hyperbaric medical association (see also to 2.10.5 below). • Current BLS training (ACLS training recommended). • Be declared medically fit to enter the chamber while under pressure.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.10.3	Chamber operators	Medical complications and emergencies require specific operator actions to mitigate additional risks and exposure to patients.	4	<p>Appropriate knowledge, training and experience are required for the operator to be able to make decisions regarding pressure control, ventilation, monitoring and termination of treatment.</p> <p>The person operating the hyperbaric chamber should be a suitably qualified chamber operator with:</p> <ul style="list-style-type: none"> • Appropriate training, as endorsed by the national hyperbaric medical association (see also 2.10.5 below).
2.10.4	Chamber attendants	<p>The chamber attendant is usually the only person with direct, immediate access to patients during a treatment.</p> <p>Proper medical training, experience and competence are essential for attendants to be able to manage patients appropriately and to undertake instruction from the medical practitioner, usually stationed outside the chamber.</p>	4	<p>The person(s) attending to patients inside the chamber should be suitably qualified to administer relevant functions with:</p> <ul style="list-style-type: none"> • Appropriate training, as endorsed by the national hyperbaric medical association (see also to 2.10.5 below). • Current BLS training. • Be declared medically fit to enter the chamber while under pressure.
2.10.5	National hyperbaric medical association	Current practices, cautions, dangers and remedial actions are made available to the HBO industry through national hyperbaric medical associations.	2	All persons involved in patient care should be current members of a recognized association or its affiliate organisation (e.g. UHMS, BNA, EBAss, EUBS, SPUMS, HTNA, SAUHMA).

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.11 Patient Care

2.11.1	Staffing levels	Chamber operations and patient complications are complex, and require a minimum complement of qualified staff (under normal as well as emergency conditions).	4 4 4 4	<p>The following minimum staffing levels should be maintained at all times:</p> <ul style="list-style-type: none"> a) The chamber operator b) At least one chamber attendant, depending on internal policies regarding extended exposure to hyperbaric conditions. c) The HBO medical practitioner who is qualified to deliver hyperbaric oxygen therapy. <p>No chamber should be left without an operator in control at any point, even in the event of a medical or other emergency that affects the delegated operator.</p>
2.11.2	Visual contact	Lack of early and appropriate diagnosis of imminent medical complications could delay the required response or treatment of a patient in distress.	4	<p>The chamber operator should have full visual access to the patient at all times.</p> <p>Medically qualified personnel (i.e., the HBO medical practitioner - or hyperbaric nurse should be able to have a direct line of vision to patients being treated.</p>
2.11.3	Medical supervision	<p>Professional expertise is required to deal with the side effects and complications of treatments and with the possibility that advanced care, life-support services, or complicated interventions might be necessary.</p> <p>Failure to provide proper medical supervision can compromise a patient's health or life.</p>	3	A qualified HBO medicine practitioner should be available at all times during all treatments and should supervise treatments in accordance with international requirements for medical supervision.
2.11.4	Patient medical screening	<p>Significant physiological risks exist for patients with contraindications if they are placed under hyperbaric pressure, especially if they are also administered oxygen-enriched gases.</p> <p>Patients may also have psychological and/or social issues that can affect their health and safety and/or the outcome of their treatments.</p>	4	<p>Every patient should be screened by a qualified HBO medicine practitioner before being accepted for treatment.</p> <p>The screening should include confirmation of the appropriateness of the treatment, the lack of any contraindications, and an assessment of the patient's physical and psychological status.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.11.5	Patient selection	<p>The inappropriate use of HBO may result in refusal of reimbursement and lack of acceptance of the treatment modality.</p> <p>Patients may be subjected to unnecessary risks where HBO is not medically indicated.</p>	2	<p>Patients should be selected for HBO treatment in accordance with the national hyperbaric medical association-approved guidelines, including the use of transcutaneous oximetry and/or other approved assessment tools.</p>
2.11.6	Patient orientation	<p>Patients who are unaware of the hazards associated with HBO treatment could inadvertently bring prohibited items or materials into a chamber.</p> <p>If patients are not well informed about the process, they may experience anxiety which could cause them to panic or experience additional stress.</p>	3	<p>Patients should receive an orientation to the HBO facility, as well as to all relevant policies and procedures, before their treatment begins.</p> <p>The orientation should emphasize safety precautions related to fire and pressure hazards (e.g., prohibited items and materials).</p>
2.11.7	Acknowledgement of safety precautions	<p>Patients may not necessarily comprehend the impact of safety precautions due to ill health or infirmity.</p>	3	<p>Acknowledgement of safety precautions should be given by patient or legal guardian in the written form.</p>
2.11.8	Written consent and informed consent	<p>It is extremely difficult to prove consent by or on behalf of a patient without a written record.</p> <p>It is also extremely difficult to prove that a patient fully comprehended the hazards and the impact of safety precautions at the time of consenting unless a fully and bilateral discussion is held with or on behalf of them.</p>	3	<p>Written informed consent should be obtained from each patient (or the legal guardian) and such written consent should be kept available in each patient's medical file.</p> <p>Before obtaining informed consent for hyperbaric treatment, the risks, benefits, and potential complications associated with hyperbaric treatment should be discussed with the hyperbaric patient or legal guardian.</p>
2.11.9	Patient care & treatment plan	<p>In order to ensure compliance with medical practices, all treatments need to be planned and documented prior to commencement of treatment.</p>	3	<p>The HBO medical practitioner should develop and prescribe a plan of hyperbaric care and this should be documented in the patient's medical record before hyperbaric treatment is initiated.</p>
2.11.10	Patient privacy	<p>Infringement of patient privacy rights may lead to legal actions against facility staff.</p>	3	<p>Hyperbaric-associated patient care procedures (such as wound care) should be performed in a manner that respects privacy.</p>

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
2.11.16	Short-term results of HBO treatments	Comprehensive information on patient response to treatment is required in order to provide a sound basis for ongoing treatments, or the cessation of treatment, where relevant.	3	For every patient, the short-term results of HBO treatment should be recorded in the patient's medical record together with appropriate objective evidence (pictures of wound, level of carboxyhaemoglobin, etc).
2.11.17	Long-term results (follow-up) of HBO treatments	The long-term sustainability of HBO for the entire industry rests upon solid medical evidence of the efficacy of HBO for specified conditions.	2	Procedures should be implemented to monitor the long-term effects of HBO treatment (follow-up) for as many patients as possible.
2.11.18	Medical alert	Immediate and appropriate reactions are required in order to deal with patients who have known conditions that could potentially lead to complications.	4	Appropriate, specific management procedures should be in place for patients presenting with conditions such as allergic reactions, diabetes mellitus, implanted cardioverters/defibrillators, movement restrictions, etc.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.12 Nursing Care and Interventions

2.12.1	Nursing care policies & procedures	<p>Nurses are responsible for several, different operations within the HBO unit.</p> <p>Without specified and documented procedures, medical review assessments may not pick up on gaps or inadequate interventions until too late to.</p>	3	<p>Written nursing policies and interventions should be developed that address the following:</p> <ul style="list-style-type: none"> • Confinement anxiety/claustrophobia • Pain related to medical or surgical problems • Infection control • Discomfort related to temperature and humidity changes inside the chamber • The potential for ineffective individual coping related to the stresses of illness and/or poor psychosocial support systems • The potential for fluid volume deficit related to dehydration or fluid shifts • The potential for alteration in comfort, fluid and electrolyte balance related to nausea and vomiting • Wound care for patients with wounds • Prevention of pressure ulcers/wounds • Safety inside the hyperbaric chamber • Management of existing medical conditions as defined in ref. 2.11.18 above.
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2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.13 Medication Control

2.13.1	Medicine dispensing	Legal requirements need to be met with regard to the dispensing of any medications.	3	Preparing and dispensing medication(s) should adhere to legal, regulatory, licensing and professional standards of practice.
2.13.2	Control of dispensed medication	Untrained and unqualified personnel may not be aware of the full ramifications of the inappropriate administering of medication.	3	Preparation and dispensing of medication(s) should be appropriately controlled.
2.13.3	Emergency medication	The lack of essential emergency medicines may compromise the safety patients or staff.	4	<p>The recommended emergency medicines that should be kept in the unit include the following (or equivalent):</p> <ul style="list-style-type: none"> • Adrenaline • Atropine • Glucose • Lignocaine/Lidocaine (if indicated in the ACLS handbook) • Amiodarone (if indicated in the ACLS handbook) • Anticonvulsant • Sedatives/anxiolytics • Aspirin • Nitrates (e.g. Angised) • Bronchodilators • Analgesics • Portable/wall oxygen • Morphine • Furosemide • Anti-emetics
2.13.4	Availability & control of emergency medication	Based on the potential for irregular and infrequent use, emergency medicines may be neglected, allowed to expire, be removed or depleted or not retained in the specified location.	3	Emergency medications should be consistently available, controlled, and secured in the hyperbaric treatment area.
2.13.5	Management of controlled substances	Staff may abuse controlled substances (i.e. medications), leading to dependency and/or the inability to manage patients appropriately.	4	Controlled substances should be managed in accordance with the regulations pertaining to the safekeeping of the medication.
2.13.6	Medical waste management	Legal requirements exist with regards to the safe disposal of medical waste, so that no infectious risk exists to persons or the environment.	4	Medical waste management should conform to the appropriate regulations for hazardous biological agents.

2. Administrative & Maintenance

Ref.	Element	Risks	RL	Minimum Requirements
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2.14 Indications and Treatments Provided

2.14.1	Approved indications	All medical services are carefully scrutinised by national regulatory authorities and professional boards. Legal liability exists where ethical practices are transgressed.	3	HBO should be provided for indications approved by the national hyperbaric medical association. Non-approved indications should be subjected to a peer-review processes
2.14.2	Treatment protocols	Treatment risks exist where internationally accepted and proven protocols are not followed.	3	Industry-accepted treatment protocols should be used for the treatment of patients, for example: UHMS, USN, Comex, the national hyperbaric medical association, etc.
2.14.3	Level of care capacity & patient selection	Unless the scope of available services is carefully defined and managed, based on expertise, equipment capability and availability, facilities may end up having to manage patients that they are not equipped to deal with.	3 3 3	a) A specific patient selection policy should be in place taking cognisance of risk-benefit ratios. b) The level of equipment, monitoring and staff experience should be considered in these policies. c) Transfer and transport issues of critically ill patients to and from the unit should be addressed.
2.14.4	Relative & absolute contraindications	Contraindications for HBO treatments are known; but facilities may not be aware of the full spectrum as well as the conditions under which these apply.	4	The list of relative and absolute contraindications to HBO treatment should be in place. Contraindications may be different for elective, chronic indications and emergency, life-treating indications

Concluding Remarks

This Guide is a compilation of relevant, available reference material related to the installation, commissioning, operation and possible modification or upgrading of a clinical hyperbaric chamber facility.

While every effort has been made to provide a thorough assessment, additional hazards may be identified with time. The same remark remains true for the NFPA 99 publication, which is also in a state of continuous improvement. As new information becomes available from HBO facilities operated worldwide, additional measures to reduce hazards may be introduced.

The author and compiler of this guide acknowledges that much of the information used has been cited or extracted from the referenced publications and further acknowledges that to the best of his professional abilities, no obvious area of risk has been left unaddressed.

Abbreviations

A	ampere
ABS	American Bureau of Shipping
AC	alternating (electrical) current
acfm	actual cubic feet per minute
ACLS	Advanced Cardiac Life Support
AHDMA	Asian Hyperbaric and Diving Medical Association
AS/NZS	Australian/New Zealand Standard
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
ATA	atmospheres absolute - 1 ATA being 101.325 kPa (14.7 psi) at sea level
atm	atmosphere gauge, with 0 atm being the atmospheric pressure at sea level
BIBS	Built-In Breathing System
BLS	Basic Life Support
BNA	Baromedical Nurses Association
CO ₂	carbon dioxide
CO	carbon monoxide
°C	degrees Celsius
CFL	compact fluorescent lamp
CGA	Compressed Gas Association
CH ₄	methane
cf	cubic feet or ft ³
dB(A)	A-weighted decibel (a measure of sound as it's perceived by the human ear)
DC	direct (electrical) current
DT	dew point (frost) temperature (at standard atmospheric pressure and temperature)
EBAss	European Baromedical Association
ECHM	European Committee for Hyperbaric Medicine
EIGA	European Industrial Gas Association
EUBS	European Undersea & Baromedical Society
°F	degrees Fahrenheit
ft	foot
gal	gallon (Imperial; 1 gal = 3.8 liters)
gpm	gallons per minute (Imperial: 1 gpm = 3.8 lpm)
GFI	ground fault interrupter (also ground fault circuit interrupter; detects current leakage to ground)
H ₂ O	water (moisture in vapor form)
HBO	hyperbaric oxygen (therapy)
HC	hydrocarbon (in liquid form)
HP	high pressure (assumed as > 1 MPa/150 psi for air and inert gases; > 0.86 MPa/125 psi for O ₂)
HTNA	Hyperbaric Technicians and Nurses Association
IPS	isolated power supply (also referred to as an isolated power system; provides electrical isolation between input and output circuits, and also provides separate ground paths)
ISO	International Organisation for Standards
kHz	kilo Hertz, a unit of frequency, also 1,000 cycles per second
LEL	Lower Explosion Limit

LIM	line isolation monitor (also line insulation monitor; used to detect ground faults in ungrounded electrical systems)
LP	low pressure (assumed as < 1 MPa/150 psi for air and inert gases; < 0.86 MPa/125 psi for O ₂)
lpm	litres per minute
LOX	liquid oxygen
LR	Lloyd's Register
MGy	mega gray (a unit of absorbed radiation dose, defined as 1 Joule/kilogram: 1 MGy = 1 MJ/kg)
MPa	megapascal - a measure of pressure
Mrad	megarad, unit of absorbed radiation dose, with 1 rad = 0.01 Gy
m	meter
µm	micrometer or 10 ⁻⁶ m, a unit of size
mA	milliamperere (0.001 A)
mg/m ³	milligrams per cubic meter (0.001 g/m ³)
mm	millimetre (0.001 m)
mW	milliwatt (0.001 watt)
min	minute
nm	nanometer or 10 ⁻⁹ m, a unit of size
NBDHMT	National Board of Diving and Hyperbaric Technology
NFPA	National Fire Protection Association
O ₂	oxygen
OCA	Oxygen Compatible Air
Pa	pascal
ppm _v	parts per million by volume
psi	pounds per square inch - a measure of pressure (also psig)
PVHO	Pressure Vessels for Human Occupancy
RCD	Residual Current Device (detects current leakage to ground; provides similar protection as a GFI)
RL	Risk Level
SAUHMA	Southern African Undersea and Hyperbaric Association
SEV	surface equivalent value (expressed in percentage or %)
SPUMS	South Pacific Undersea Medicine Society
UV	ultraviolet light (light spectrum immediately below visible light, wavelength range 10 - 400 nm)
UHMS	Undersea & Hyperbaric Medical Society
USN	United States Navy
USP	U.S. Pharmacopoeia
V	volt
V _{AC}	volts alternating current
V _{DC}	volts direct current
V _{rms}	root mean square voltage
W	watt

Appendix A

Determination of Risk Levels

As referred to in the explanatory notes, a *risk* may be quantified by the product of the *probability* (quantified by the likelihood of occurrence), the *exposure* (quantified by frequency of exposure where it applies) to a hazard, and the potential *negative consequences* (quantified by severity).

In all cases, a realistic assessment should be made of the actual quantification of each of the three elements: a realistic worst-case scenario should be considered as to the severity.

The Likert scale provides a suitable means of allocating scores to each element; the probability of fire, mechanical or health risks should be considered for each hazard assessed.

A score is thus computed as the product of each of the three elements: e.g. 5 x 5 x 5, or 125, being the highest score.

The three tables immediately below provide relevant descriptions for the quantification of probability, frequency of exposure and consequence.

Probability/likelihood of an event (incident or accident) occurring					
Fire and explosion		Mechanical hazards		Physiological & Medical Hazards	
Combustion definite	5	Failure definite	5	Event definite	5
Combustion expected	4	Failure expected	4	Event expected	4
Combustion possible	3	Failure possible	3	Event possible	3
Combustion unusual	2	Failure unusual	2	Event unusual	2
Combustion unlikely	1	Failure unlikely	1	Event unlikely	1

Exposure to the hazard		Severity of the outcome	
Continuous: an entire shift	5	Catastrophic: e.g. death; life-threatening injury; destruction	5
Daily: < say twice a day	4	Severe: e.g. significant injury; facility no longer available	4
Weekly: < say twice a week	3	Serious: e.g. reduced ability to treat/treatment quality	3
Monthly: < say twice a month	2	Significant: e.g. minor damage/injury; additional staff needed	2
Annually: < say twice a year	1	Noticeable: e.g. inconvenience; additional work required	1

It is possible to have no exposure to a hazard, or no consequences. In this case there is no risk.

Where a risk includes more than one of the probability risk categories (fire and explosion, mechanical hazards or physiological & medical hazards), each should be assessed separately (probability x exposure x severity) and the highest score used.

The next table provides empirically-derived guidance to the determination of a risk level, based on scoring probability, exposure and consequence, the associated risk rating, and requirement for mitigation based on urgency to avoid consequence.

Score	RL	Risk Rating	Requirement
> 100	5	Very high	<p>Attention and risk mitigation are critical and must be given highest priority.</p> <p>A potentially dangerous situation may exist, with the possibility of very serious/catastrophic consequences in the event of an incident.</p> <p>The treatment activity should stop immediately and should not recommence until effective mitigation is in place.</p>
60 - 99	4	High	<p>Attention and risk mitigation are required and must be given high priority.</p> <p>A serious situation may exist that could endanger people or equipment or could seriously disrupt or jeopardize the facility.</p> <p>Various solutions or actions may mitigate the risk, considered at the discretion of the Safety Officer, but they should be recorded in writing.</p>
20 - 59	3	Medium	<p>Attention is required.</p> <p>Eventual exposure to this risk could likely result in an incident. At the very least, outcomes may include business disruption, financial or liability consequences, injuries, or equipment damage.</p> <p>Mitigation of the risk should be accomplished within practical time and cost considerations.</p>
10 - 19	2	Low	<p>Attention is recommended for the optimal functioning of the hyperbaric facility.</p> <p>Risk mitigation steps already in place should at least be recorded.</p>
< 10	1	Very low	<p>The risk is acceptable.</p> <p>Note should be taken of the risk, but either it has already been suitably mitigated or the impact is of justifiably low significance.</p>

Appendix B

Guidance on Chamber Air Specifications

Introduction

A great deal of confusion exists over the so-called minimum specifications for air - both breathing and medical grade. This is partly due to the fact that air is often stored in HP form, requiring additional corrosion considerations and therefore mandating uncomfortably dry air. However, the major debate centres on the safety aspects regarding the presence of HC and the definition of *oil-free* air.

National standards for air purity (based on acceptable impurity levels) do exist in most countries. However, these standards are not necessarily appropriate for oxygen-enriched environments found in hyperbaric chambers, necessitating a review of the international standards that are applicable.

The NFPA 99 standard requires air that is both oxygen-compatible and medically safe. The resultant standard is classified as Medical Air (as defined by U.S. Pharmacopoeia or USP), with additional restrictions.

Although most national standards require stricter control of (H₂O), this is based on storage cylinder corrosion requirements, as opposed to patient considerations or oxygen-safety factors.

The following standard allows a greater amount of H₂O to be present in air up to 4.0 MPa (580 psi) as do many of the international diving standards for surface-supplied air. It is important to note the additional requirements for air compressed to higher pressures, required to avoid the risk of regulator freeze.

Specification

The required minimum specification air to be supplied to Class A chambers is:

Element	Requirement			
O ₂	20% to 22%			
Moisture	Compressed air for HP cylinder storage should meet the requirements of:			
	< 50 mg/m ³ (62 ppm _v) or DT -46° C (-51° F) for cylinder pressures of between 4 - 20 MPa (580 - 2900 psi).			
	< 35 mg/m ³ (44 ppm _v) or DT -49° C (-56° F) for cylinder pressures of between 20 - 30 MPa (2900 - 4350 psi).			
	< 25 mg/m ³ (33 ppm _v) or DT -51° C (-60° F) measured at the compressor outlet.			
	Air supplied to the chamber downstream of all pressure reducing regulators need only meet the following requirements, except for applications where the air passes through pneumatic controls. In these cases, a 62 ppmv (-46° C/-51° F dew point) limit may be required.			
	Supply pressure MPa (psi)	Max H ₂ O content* mg/m ³ (ppm _v)	Supply pressure MPa (psi)	Max H ₂ O content* mg/m ³ (ppm _v)
	0.5 (72.5) 1.0 (145) 1.5 (220) 2.0 (290)	290 (361) 160 (199) 110 (137) 80 (99)	2.5 (360) 3.0 (435) 4.0 (580)	65 (81) 55 (68) 50 (62)
*Measured at 1 ATA & 20° C (68° F)				
CO ₂	CO ₂ to be less than 500 ppm _v (required where breathing pressures may exceed 1 ATA).			
CO	CO to be less than 5 ppm _v			

Element	Requirement
Oil	<p>As a liquid, oil is to be non-detectable.</p> <p>Liquid oil content is defined as a level of condensed HC, measured in mg/m³ at normal temperature and pressure. The lowest detectable level is 0.1 mg/m³.</p> <p>Where oil-lubricated compressors must be used, irrespective of the filtration system employed, the incoming chamber air supply should be continuously monitored downstream of the filters for oil content.</p> <p>Gaseous HCs, for example, methane (CH₄) are to be less than 25 ppm_v.</p>
Particulates	Concentration of particles to be < 0.5 mg/m ³ for particles greater than 5 µm in size.
Odor	None

Appendix C

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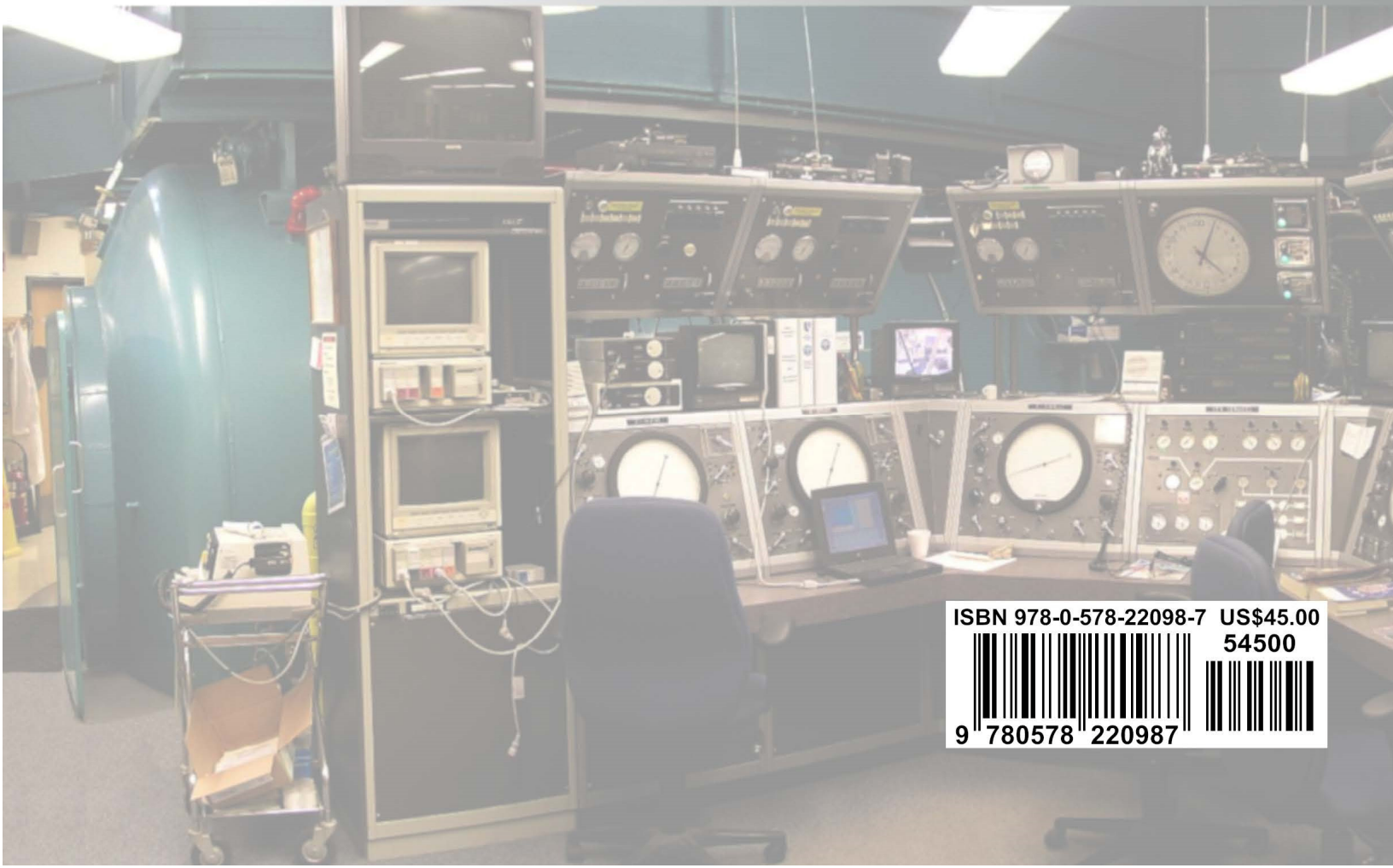
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- Member, UHMS Materials Testing Advisory Committee
- Member, National Fire Protection Association Technical Committee on Hyperbaric and Hypobaric Facilities (HEA-HYP)
- Member, International Congress on Hyperbaric Medicine Scientific Committee (2011, 2014, 2017)
- Member, European Committee for Hyperbaric Medicine: Code of Good Practice
- Member, South African Bureau of Standards Committee for Pressure Equipment
- Member, American Society of Mechanical Engineers Pressure Vessels for Human Occupancy Committee on Design & Piping



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