Ref.	Actual Determined Hazard or Risk	Minimum Requirements
1.	**Housing of Monoplace Facilities**	
1.1	Standard for Health Care Facilities: The overall risks identified include: fire safety, building safety, mechanical equipment safety, personnel and operational safety.	National statutory regulations, standards and local authority bylaws for healthcare facilities must also be adhered to, specifically for fire safety, building and general facility aspects. Chapter 14 of NFPA 99 addresses all the risks on a thoroughly integrated and comprehensive basis, and is specifically relevant to hyperbaric facilities.
1.2	Size of rooms: Inadequate room size presents accessibility risks during both routine and emergency situations, thereby compromising patient care and health.	Single monoplace chambers require a room at least 3.3 m wide by 7.2 m long. Dual monoplace chambers require a room at least 6.7 m wide by 7.2 m long.
1.3	Chamber orientation: Restrictions to egress from the chamber during emergencies are hazards.	Chamber orientation should allow immediate egress from the chamber, ease of patient transport as well as emergency evacuation.
1.4	Emergency configurations: Emergency extraction of patients.	Decompression and removal from a monoplace chamber should be achievable within 2 minutes.
1.5	Location (position) of operator: Where one operator is required to manage two chambers, impaired visibility could affect patient safety.	Operators should be located with the control for both units within sight and reach at all times. This is usually achieved by mounting one of the chambers in the reverse direction, or by using a reverse-mounted control system for one of the chambers.
1.6	Space for emergency procedures: Inadequate space to handle cardiac arrests, seizures or other patient medical complications will severely compromise the patient's health. Resuscitation equipment such as defibrillators may present an additional hazard where high oxygen concentrations are present.	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 2m from the open door of the chamber.
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.	Rooms housing HBO facilities should be for the exclusive use of the facility. Ancillary equipment may be housed within these rooms.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
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.	All supporting foundations should be strong enough to support the chamber during all intended operations, preferably including hydrostatic pressure testing (where applicable). 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. Ground floor location of the chamber is the preferred option.
1.9	Flooring: Conductive flooring	Conductive flooring is not mandatory for monoplace chamber treatment facilities.
1.10	Floor wax/polish: Commercial floor polishes and waxes often contain hydrocarbons and also impede conductivity with the floor.	Floors should not be coated with hydrocarbon-based products that may be entrained into the chamber. Coatings should also not affect the conductivity of flooring.
1.11	Static electricity: Unsuitable flooring will result in a build-up of static electricity, providing a source of sparking as well as a cleanliness risk.	Clinical or hospital flooring is generally compliant in this regard, comprising (conductive) tiling, linoleum or treated concrete. Regular cleaning in accordance with clinic/hospital procedures should be performed.
1.12	Room temperature: Humidity and temperature control affect static electricity, as well as patient comfort and operator attentiveness.	Rooms housing monoplace chambers should be provided with air conditioning for compliant temperature and humidity control (ref. 4.29).
1.13	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 leave the room.	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. All interconnecting doors should be rated as at least 1½ hour fire doors.
1.14	Fire protection of rooms housing the chamber & ancillary equipment: A fire in the chamber or equipment room may endanger: 1) the facility staff and patients, both inside and outside the chamber; 2) the operators, preventing them from remaining at their posts during the required emergency termination and evacuation process; 3) the chamber and ancillary equipment; 4) the continued operation of ancillary equipment, preventing safe termination of the treatment; & 5) the remainder of the health care facility.	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. Mobile, temporary facilities and facilities housing chambers that are not fixed to the foundations are excluded from these requirements. Alternatively, where this is not deemed to be a requirement, at least two portable fire extinguishers should be strategically located within the room. *Note: Minimum national regulations take precedence although it remains a strong recommendation that a sprinkler system should be installed.*

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
1.15	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 occupants. The system must also prevent spreading of the fire to other parts of the health care facility.	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.
1.16	Facility fire protection equipment: Failure of any of the facility fire suppression system control equipment will jeopardise the ability of the system to effectively extinguish a fire.	Semi-annual inspections of extinguishing media and full system functioning should be conducted.
1.17	"No Smoking" signs: Any source of open flame presents a hazard in a location where the possibilities of high oxygen concentrations exist.	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.
1.18	Lighting (UV): Certain ultraviolet light results in deterioration of the chamber acrylic tubes. Direct sunlight, mercury vapour discharge and certain types of fluorescent lighting are known sources of detrimental UV radiation.	Monoplace chamber acrylic 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 wavelength above 320 nm).
1.19	Lighting: Flickering lighting may affect patients with higher flicker fusion thresholds, inducing eyestrain, headaches and fatigue.	Controlled incandescent lights or dimmable fluorescent lighting fitted with electronic ballast (20 – 60 kHz frequency range) are suitable for use.
1.20	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.	The HBO facility should be linked to the clinical facility by means of a telephone extension, as well as an intercommunications unit linked to the administration office.
1.21	Cleanliness: Apart from health risks, greases, oils and dirt present additional fire hazards in areas where high oxygen concentrations may be present.	The HBO facility should be cleaned regularly to the satisfaction of the Medical Director.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
2	**Design and Construction of Monoplace Hyperbaric Chamber**	
2.1	Design of Hyperbaric Chambers: Use of inadequate, inappropriate and unsuitable safety standards will compromise operator, patient and facility safety, will compromise the safety of the remainder of the health care facility, and will result in non-compliance with statutory instruments and appropriate regulations. Pressure vessels are classified as hazardous items of equipment. An applicable Safety Standard incorporated under national regulations for Pressure Vessels should be used.	Chambers should be designed to meet the requirements of any one of the approved safety standards incorporated into the national occupational health and safety legalisation, provided that the standard selected is applicable to pressure vessels for human occupancy (including in particular, requirements for the viewport design). In addition, an internationally accepted life-support standard should be used to determine chamber equipment requirements, ancillary equipment requirements, levels of redundancy, safety systems and maintenance requirements. All chambers, viewports and all ancillary equipment, including the complete installation thereof, should be inspected and certified as compliant with the relevant standard by an approved inspection authority.
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.	These hazards will be addressed where compliance with the requirements of the appropriate safety standard, international guidelines for vessels for human occupancy, legal statutes and insurance companies is achieved, and demonstrated through certification by an approved inspection authority. A copy of the original certification document should be retained at the facility.
2.3	Internal surface treatment or finish of chamber: Chemically unstable, flammable and habitat-unsuitable finishes will present both health and fire hazards.	The interior of the chamber should either be untreated, as in the case of stainless steel, or be treated with inorganic, chemically stable and preferably flame resistant epoxy paint, suitable for human occupancy and hyperbaric pressure applications.
2.4	Off-gassing of paint: Initial off gassing of curing painted surfaces presents a health hazard.	No chamber should be used within the first 72 hours after application of the internal surface treatment, unless otherwise specified by the paint manufacturer.
2.5	Sound deadening materials: Certain sound deadening materials present a fire hazard.	Where sound-deadening materials are used within the hyperbaric chamber, such materials should be flame resistant.
2.6	Sufficient number of viewing ports & access ports for equipment: Inadequate allowance during initial design and manufacture may result in impaired visibility of patients and compromise safe installation of monitoring and treatment equipment.	The initial design of the chamber should include a sufficient number of viewports and equipment access ports for piping, equipment and monitoring leads. A suitable guide is to allow for at least 50% excess capacity of access ports or penetrations.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
2.7	Location of penetrations: Acrylic tubes are not designed 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.	No acrylic tubes should be modified from the original design and construction. 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.
2.8	Viewport (acrylic tube) design: Viewport design and maintenance is a safety critical element and falls outside of the scope of many international codes of design and construction.	Viewports should be designed to meet the requirements of a safety standard that makes specific provision for non-metallic, pressure-bearing structures. 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 competent person for use in a protected service environment.
2.9	Protection of acrylic tube & window(s): Acrylic tubes and/or windows are generally used to provide adequate visibility of the patient. Acrylic is easily scratched, obscuring vision, or damaged, reducing life span (due to reduction in design wall thickness), through surface contact and impact.	Outer protective tubes or linings should be considered to limit mechanical damage to the inner, pressure bearing tube.
2.10	Failure of acrylic tube: Defined mechanical hazards are associated with the failure under pressure of any part of the pressure envelope. The acrylic tube represents the largest single pressurized section of a hyperbaric chamber.	Outer protective tubes are generally used to maintain integrity of the primary pressure bearing acrylic viewport. These should not be considered as pressure bearing, but may act as a mechanical barrier allowing controlled decompression in the unlikely event of an inner tube failure. Outer protective tubes may result in smaller wall thickness for inner tubes being acceptable.
2.11	Door seals: Any damage to a door seal may result in chamber gas escaping under pressure, introducing a high oxygen concentration hazard.	Chamber O-rings seals should be easily repairable. Operators should be trained to identify leaks at door seals and to inspect the seal integrity before and after treatments. Spare O-ring seals should be maintained in the facility.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
2.12	Pressure relief valve: Over-pressurization of a chamber represents a serious mechanical and subsequent fire hazard. Insufficient venting capacity of relief valves is a pressure vessel hazard. Malfunctioning relief valves can compromise the safety of occupants.	Each chamber should be fitted with an over-pressure relief valve, designed and tested under regular inspection authority survey to prevent the chamber pressure from exceeding the allowed working pressure by more than 10%. Over-pressure relief valves should be sized such that no situation can exist whereby gas can be introduced faster than can be discharged. The reseat pressure limit should be no lower than 10% below set pressure and this function should be tested regularly. In the case of oxygen-filled monoplace chambers, the discharge from the safety valve should be connected to an exhaust line piped into a safe open space (i.e. not terminate near any heat or ignition sources, or hazardous areas). Relief valves should be fitted with external isolating valves to allow for shutting off in the event of malfunctioning. Valve handles should be wired in the open position using breakable safety wire. Internal ports should not be blocked or obstructed in any way other than with a suitable anti-suction device.
2.13	Pressure gauges: Inability of operators from reading chamber pressure may affect the quality and safety of treatment for both patient and staff. Correct installation, control and maintenance of gauges all affect the effective functioning thereof.	All chamber compartments should be fitted with an independent pressure gauge enabling pressure to be read by operators. This is usually achieved using control panel mounted gauges. Pressure gauge lines should not supply any other devices. Internal ports for gauge lines should be protected with a shield to prevent inadvertent blockage. All systems should be correctly cleaned prior to use, and regularly checked for leaks. Gauges should be calibrated at least once a year to ensure accuracy.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
2.14	Materials: Fibreglass contains bonding agents that deteriorate with time, providing a source of highly combustible materials.	Fibreglass should be avoided for use within a monoplace chamber.
	Conductive flooring: Unsuitable flooring materials are a known source of building of static charges.	Conductive flooring as pertaining to anaesthetizing locations within health care facilities should apply.
	Oxygen equipment compatibility: Many items if ignited within a pressurised, oxygen-enriched atmosphere are not self-extinguishing.	Only approved, dedicated oxygen containers, control mechanisms, interconnecting hoses and fittings, valve-seat materials and lubricants may be used. International guides for determining the suitability of materials for oxygen compatibility should be adhered to. Static conditions and impact conditions are both applicable. ASTM (American Society for the Testing of Materials) and NFPA guidelines for design using oxygen compatible materials should be followed.
	Oxygen cleaning: Contamination of oxygen equipment may present a fire or explosion hazard.	Oxygen equipment, including fittings, connections, gas handling equipment, etc. should all be oxygen cleaned prior to use. Oxygen cleaning requires special considerations and only approved procedures may be used.
	Oxygen lubricants: Hydrocarbon lubricants are a known source of fuel.	Only oxygen compatible lubricants may be used inside the hyperbaric chamber.
# 1	Note 1: 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™.	
3	**Illumination**	
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.	The preferred location for the mounting of chamber lighting is on the outside. Where lighting is to be supplied inside the chamber, it should be supplied from external sources (cold lighting).
3.2	Temperature of external lighting fixtures: Where lights are used in conjunction with viewports, excessive surface temperatures will compromise the integrity of the viewport acrylic material.	Lighting fixtures should be designed in accordance with the requirements of a suitable standard containing such provisions. Viewport temperature ratings should be considered during the design of such fixtures.
3.3	Emergency lighting: Failure of chamber illumination may result in hazards to both patients and medical personnel performing procedures. In addition, any emergency responses will be hampered, thereby creating additional hazards.	Chambers should be fitted with sufficient lighting fixtures so as to provide suitable redundancy in the event of single failures. Where chambers have sufficient viewports, external room lighting may be sufficient to provide the minimum illumination required. In addition, lighting power circuits should be connected to the chamber or health care facility's emergency power supply.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4	**Gas Supply Systems, Ventilation and Chamber Air Conditioning**	
4.1	<u>Internal breathing apparatus</u>: Ineffective supply of therapeutic gas compromises the quality of treatment and will affect the outcome of the patient.	Where this is fitted, the breathing apparatus and supply system should be designed such that: 1) it is independent of chamber atmosphere; 2) it is fully functional at all chamber operating pressures; 3) where a demand system is used, it is capable of sustaining a supply pressure of at least 0.35 MPa above chamber pressure; 4) where an 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 5) in the event of fire, the supply can be switched to air (or a suitable, normoxic mixture).
4.2	<u>External self-contained breathing apparatus</u>: 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 occupant to safety.	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. Suitable eye protection from combustion products should be incorporated into the breathing air set.
4.3	<u>Air chamber ventilation requirements</u>: In air chambers, inadequate ventilation rates impact on patient condition, allow a build-up of oxygen and carbon dioxide, and affect temperature and humidity. These conditions introduce fire and toxic gas level hazards, as well as the hazards associated with poor temperature and humidity conditions. Furthermore, these hazards exist during all stages of chamber operation, i.e. pressurisation, constant pressure and depressurisation.	A minimum* ventilation rate of 85 *actual* litres per minute per chamber occupant is required (*actual* flow implies the rated flow at the chamber's ambient pressure and temperature). This rate may be reduced when the occupant is breathing oxygen using an overboard dump system, providing that oxygen levels remain below 23.5%. The minimum ventilation rate should always be implemented when a mask is not being used by the occupant(s) – such as during an air-break. **The ventilation rate will 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%. The guidelines for oxygen chambers specified under 4.4 below should be adhered to.* Inlet & exhaust points should be located so as to ensure effective circulation, scrubbing out of unwanted gases, lowering of the chamber internal temperature & reduction of humidity levels. Also, stable conditions may be maintained by scrubbing to remove carbon dioxide and odour levels.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.4	Oxygen chamber ventilation requirements: Purge rates can have a detrimental effect on patients. Patients with large burns could suffer unacceptable evaporative heat loss making them hypothermic.	During the initial pressurization period, the chamber needs to be purged rapidly to remove all nitrogen from the initial air charge. A purge rate of at least 240 litres per minute will ensure that the ambient oxygen levels rise rapidly. Based on the size of the chamber, this rate may be reduced to the minimum level of 85 actual litres per minute for the remaining duration of the treatment. As it is often impractical or unsafe to change purge control systems, medical staff should be aware of specific patient requirements and provide appropriate, alternative or compensatory measures. Inlet & exhaust points should be located so as to ensure effective circulation, scrubbing out of unwanted gases, lowering of the chamber internal temperature & reduction of humidity levels. Recycling gas systems also allow for lower purge rates. Purge rates may be safety reduced for specific patients through the use of close fitting facemasks.
4.5	Source of air for chambers: Toxic, flammable or fouled air may be introduced into the source of air, beyond the control of the facility operators.	Compressor intakes should be so located that toxic, flammable or fouled air cannot be introduced. Typical sources of fouling include areas of vehicular activity, internal combustion engines, equipment, & building exhaust outlets. Warning signs should be posted at the locations of such intakes.
4.6	Handling of air for chambers: Unsuitable or malfunctioning air handling equipment may contaminate the air supply to the chamber. Oil and other hydrocarbon contamination present an extremely dangerous situation where oxygen-enriched atmospheres exist.	Air supplies to the chamber should be monitored as detailed under the succeeding par. on Chamber Air Supply Monitoring (1.7.9). Efforts should be taken to ensure that known contaminating causes are eliminated. This includes correct maintenance and regular inspections of compressor seals, air purification devices and compressor intakes and filters.
4.7	Use of oil-lubricated compressors: Air-treatment package failure, inadequate maintenance or compressor system failure may introduce oil and other hydrocarbons into the chamber air supply. This presents a major fire hazard, especially in pure oxygen or oxygen-enriched atmospheres.	The use of oil-lubricated compressors is strongly discouraged. If oil-lubricated compressors are used, these should be fitted with air-treatment packages specifically designed to produce medical air (ref. par. 7.9). In addition, there should be automatic safeguards in place to prevent downstream contamination. Oil-lubricated compressors and the associated air-treatment packages should be diligently monitored and maintained.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.8	Gas quality: Unknown or non-certified gases may introduce flammable or combustible compounds into the chamber. Calcite crystals are known by-products of water-based lubricants used in certain oil-free (Teflon ring) gas compressors.	Hydrocarbon and 5 micron particulate in-line filters should be used to remove contamination - preferably 1 micron filters where non-certified or suspect gas supplies are provided, from air, oxygen and gas mixtures.
4.9	Gas moisture content: Excessive moisture affects the ability of most filtration systems to work effectively. Condensed moisture will also influence control valves, and will result in accelerated corrosion in storage vessels.	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.
4.10	Use of anaesthetic agents: Toxic or flammable gases, if introduced, constitute a patient hazard as well as a fire risk.	Inhalation anaesthetic agents should only be used with closed-circuit breathing apparatus, which employ overboard dumping. Flammable anaesthetic agents should not be used.
4.11	Oxygen purity standards: Impure or contaminated oxygen is both a health, as well as a fire risk.	Medical oxygen requires a purity level of at least 99.5% (Ph. Eur.). Under no circumstances should any oxygen other than that piped from a cryogenic source, or from high-pressure cylinders - certified as medical grade oxygen, be used. Where a facility cannot be guaranteed of a pure supply, the supply to the chamber should be analysed either continuously when on-line, or at the discretion of the Medical Director, or at least when supplies are changed-over or refilled.
4.12	Air supply system volumetric/capacity considerations: Insufficient air capacity for non-routine or emergency treatments will compromise patient care during inadvertent power breaks affecting the compressor.	Air compressors and storage vessels should be designed with sufficient capacity to complete the maximum-duration medical treatment, including air-breaks and/or air supply during decompression phase. Air chambers require sufficient air for pressurisation and maximum ventilation requirements.
4.13	Oxygen supply system volumetric/capacity considerations: Correct volumetric considerations are essential for effective treatment as well as preserving the health care facility's other requirements.	Required design considerations include: 1) Required volume of oxygen to pressurise and ventilate the chamber. 2) Facility supply should be large enough to support complete treatment. Note: One litre of liquid oxygen evaporates to 860 litres of gas at standard temperature and pressure. 3) Supply piping should be sized to support chamber maximum flow demand without affecting the health care facility's other requirements.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.14	Emergency or back-up supply: Interruption of oxygen supply could compromise treatment as well as patient condition.	A secondary (reserve) supply of oxygen should be provided in the event that the main service is interrupted. Use of limited quantities of high-pressure oxygen, suitably regulated, is usually deemed sufficient.
4.15	Stored gases: Large quantities of stored gas, especially oxygen, represent a difficult control situation. Such units are hazardous in fire situations and require regular inspections for leaks, etc. Pressurised containers are a recognised hazard.	The amount of oxygen stored in or around the hyperbaric facility should be kept to the minimum required to complete treatments, or to deal with emergency situations. Pressurised containers may only be introduced into the hyperbaric chamber where they are approved for use, such as emergency gas supplies.
	Facility supply requirements	
4.16	Liquid oxygen storage tank: Volumetric sizing considerations are essential for effective treatment as well as preserving the health care facility's other requirements.	The liquid oxygen supply company should do correct storage tank sizing. As a guideline, a supply system would be based on pressurisation requirement (volume times depth in ATA) plus ventilation for the 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.
4.17	Cryogenic supply system: Inadequate maintenance, poor housekeeping and lack of regular inspection of the cryogenic supply systems present fire, failure and supply risks to the facility. While supply and scheduled maintenance may be the responsibility of other departments, or an outside vendor, due care and attention is still the responsibility of the facility in order to preserve the integrity, safety and availability of the hyperbaric unit.	Where a cryogenic supply system is installed, this should conform to local statutes, be controlled & managed by a competent gas supply company, and be properly maintained at least in respect of the following aspects: 1) appropriate security of the site to prevent unauthorised access or interference; 2) routine addressing of all fire hazards, such as removal of under- or overgrowth, overhead electrical supply lines, or burnable materials (including waste matter, organic, asphalt and petroleum products) stored in the immediate vicinity; 3) placing and integrity of adequate warning signs and emergency instructions; 4) regular inspection (at least prior to each treatment session) of the cryogenic storage area, including monitoring of liquid/gas storage levels, system pressures, position of controls, condition of the equipment and security of the site; and 5) appropriate and regular maintenance by the appointed, competent gas supply company.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.18	Piping materials: Cryogenic operating temperature requirements compromise the strength and integrity of many standard materials.	Materials used for liquid oxygen equipment should be selected on the basis of low temperature characteristics as well as compatibility and cleanliness. Copper, austenitic stainless steel and monel are considered suitable. All pipeline designs should be undertaken and approved by a competent engineer. Liquid oxygen piping should be insulated.
4.19	Pipe sizing: Incorrectly sized pipelines will compromise treatments, patient condition as well as the health care facility's other requirements.	Pipelines to the HBO treatment facility should be sized according to the maximum demand requirement - typically 20 mm for a required flow per chamber of 700 l/min. Pipe length has a direct bearing on size, as pressure loss is directly proportional to length. Longer lengths may require compensation for pressure losses by increasing diameter. The system manufacturer usually specifies pressure available at the chamber. As a guideline, chambers require a minimum of 0.35 MPa, or 0.41 MPa where a ventilator is fitted. Maximum pressure is usually limited to 0.55 MPa. Oxygen supply lines should have a safety shut-off valve immediately adjacent to the treatment area and readily accessible to the facility personnel.
	Chamber piping considerations	
4.20	Oxygen supply control panel: Control of oxygen supply is essential for safe and effective treatments, as well as during emergencies.	A separate oxygen supply point and shut-off valve should be provided for each chamber.
4.21	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.	A downstream 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 calibrated at least once a year to ensure accuracy and to assist in chamber maintenance and calibration procedures.
4.22	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.	An in-line filter should be installed immediately prior to the chamber control system. A 10-micron filter with a flow capacity of at least 850 l/min and rated at 1.5 times the maximum line pressure should be used.
4.23	Oxygen toxicity: Oxygen toxicity is a known contra-indication of this form of treatment. Planned air breaks reduce the susceptibility to oxygen toxicity.	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.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.24	<u>Accidental mixing of gases</u>: Accidental mixing of oxygen and air will compromise the treatment efficacy, as well as compromise patients being treated for toxicity symptoms.	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.
4.25	<u>Piping systems</u>: Certain materials are not suitable for hyperbaric facilities due to impurities and corrosion considerations.	Only* copper, brass alloys, or stainless steel alloys should be considered for supplies to the chamber. In selected cases*, the use of flexible hoses is acceptable, strictly subject to the criteria detailed in 4.27 below.
	Undersized piping systems affect patients by prolonging treatments unnecessarily, restricting extraction of patients during emergencies, and generating excessive noise.	Piping systems should be designed provide the maximum flow required under all conditions. Refer to the requirements specified in par.4.19 above. Exhaust systems should be capable of surfacing (decompressing) the chamber from 3 ATA to ambient pressure in less than 2 minutes.
	The use of high pressure supplies may result in the over-pressurisation of piping and components, not intended for elevated pressures. Inadvertent exposure to high pressure may also be introduced where control equipment fails, or where operators fail to control pressures correctly, using the equipment provided.	Chambers should only be pressurized using regulated, low pressure gas, in accordance with manufacturer's specifications. *High pressure gas supplies, i.e. > 4 MPa, should be reduced as close to the source as is practical.* All pressure reducing regulators, used to reduce high pressure gases, should be fitted with downstream pressure relief devices in order to protect piping and components rated for lower pressures.
	Dirt particles are a known source of failure of regulators to maintain constant downstream pressure.	The inlets to all pressure reducing regulators should be fitted with suitably sized particle filters (≤10 µ) to prevent dirt from entering the sensing ports and causing downstream regulator creep.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
	Piping Systems - continued Systems design that rely on operator attentiveness to avoid back-filling of storage vessels that may be at different content levels, or to prevent reverse pressure or flow situations – specifically where diaphragms and sensing equipment are installed, or protect against unplanned venting through unintended flow-paths, can all lead to compromised supplies, inaccurate assessments of available gases, or failure of pressure control equipment.	Piping 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.
	All venting systems can cause injuries to patients where inlets are not suitably screened.	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.
		All shell-penetrations should be fitted with external isolating valves to allow for shutting off of gases in the event of malfunctioning. *(It is accepted than modern, automatically-controlled systems do not provide for this feature: the responsible person will need to make an appropriate risk-mitigating decision in this regard.)*
	Inappropriate or inadequate cleaning procedures may result in premature component failure, introduction of toxic vapours or even an increased fire hazard.	All system components and piping should be cleaned using an approved, oxygen-cleaning procedure prior to first use.
	Failures of computer or remote pneumatic control systems are complex and can easily result in loss of control.	All computerised or remote control systems should be designed with adequate back-up facilities as well as manual overrides.
4.26	<u>Oxygen piping</u>: Compressed oxygen contains both fire as well as stored energy hazards.	Only competent and thoroughly trained persons may install, clean or work on any oxygen piping systems.
	Inappropriate or inadequate cleaning procedures may result in premature component failure, introduction of toxic vapours or even an increased fire hazard.	Where copper tubing is brazed, it should be continuously purged using nitrogen to prevent the formation of hazardous copper oxides. All oxygen supply lines should be cleaned in accordance with an approved oxygen cleaning procedure.
	Certain materials are not suitable for oxygen applications.	Only oxygen compatible materials may be used – ASTM, CGA and ASME/PVHO publications contain lists of approved materials.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
	In the event of a location fire, the oxygen supply to the chamber room would provide an additional hazard of further feeding the fire.	An oxygen shut-off valve should be installed at the point where the oxygen enters the room.
	Rapid acting valves are a potential source of adiabatic heating during opening and closing.	Piping systems with pressures below 0.86 MPa may be isolated using quick acting ball valves. **However, ball valves should not be used for the isolation of lines containing oxygen at pressures above 0.86 MPa.**
	Oxygen piping - continued	Oxygen supply pressure to the chamber should be monitored at the control panel.
	The use of high pressure supplies may result in the over-pressurisation of piping and components, not intended for elevated pressures. Inadvertent exposure to high pressure may also be introduced where control equipment fails, or where operators fail to control pressures correctly, using the equipment provided.	Oxygen supplies at pressures above 4 MPa, should be reduced at source, or, if this is impractical, at the chamber control station. All pressure reducing regulators, used to reduce high pressure oxygen, should be fitted with downstream pressure relief devices in order to protect piping and components rated for lower pressures. The inlets to all pressure reducing regulators should be fitted with suitably sized particle filters (≤10 µ) to prevent dirt from entering the sensing ports and causing downstream regulator creep.
	Systems design that rely on operator attentiveness to prevent: back-filling of storage vessels that may be at different content levels; or reverse pressure or flow situations – specifically where diaphragms and sensing equipment are installed; or unplanned venting through unintended flow-paths; can all lead to compromised supplies, inaccurate assessments of available gases, or failure of pressure control equipment.	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. 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. Only special, dedicated tools should be used for oxygen service (i.e. cleaned and non-sparking).

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.27	Flexible hoses: Flexible hoses are less secure than rigid piping, require additional protection from mechanical damage, and are generally more prone to failure.	The use of flexible hoses should: 1) be kept to a minimum, except for exhaust lines; 2) be restricted to short lengths where used for high pressure gas applications; 3) be correctly selected for compatibility and cleanliness for the gas being transported; 4) suitably rated and appropriately certified for the system design pressure; 5) be connected without any stress on joints and couplings; 6) be assembled without kinks or sharp bends; 7) be adequately protected from external, mechanical damage; 8) not pose a trip hazard, and 9) be used only where adequate provision has been made for the regular inspection of the condition of all flexible hoses.
4.28	Sound attenuation: The chamber environment presents numerous acoustic problems that serve to magnify noise levels.	Mufflers should be used to reduce noise to the levels required by national regulations - typically less than 85 dB(A) as an occupational limit or during peak pressurization or depressurization rates. Noise should be less than 70 dB(A) around the patient's head during the actual treatment period. Reverberation should be reduced by the effective use of baffling panels, constructed using suitable fire-resistant materials.
4.29	Oxygen exhaust system: Uncontrolled exhaust of oxygen constitutes a physiological and fire risk.	The design of the exhaust equipment should: 1) be fitted with emergency isolation valves, preferably fitted close to the shell; 2) contain a line length of no longer than 5 metres unless sized to eliminate gas flow back-pressure; 3) preferably be separate from any other exhaust lines; 4) be designed to restrict or control the flow between the patient and ambient pressure; 5) contain no flow obstructions at or near the outlet; and 6) not terminate near any heat or ignition sources, or hazardous areas.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
4.30	Conditioning of chamber gas: 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.	Chambers shall be maintained at temperature and relative humidity levels required by local or national regulations for anaesthetising locations. Chambers should ideally be maintained at a temperature of 22° ± 2°C and a relative humidity of 50% to 70 %. This can be achieved through the use of ventilation using suitably conditioned gas. Alternatively, suitably designed and approved chamber environmental conditioning units may be used. (Simple water-medium radiator-type heat exchangers with thermistor controls should be used.)
5	**Fire Protection**	
5.1	Fire protection for monoplace chambers. NFPA-99 specifically states that there are no fire protection (extinguishment) requirements for monoplace. (*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 occupant*.)	Fire risks have to be dealt with by operators on the outside. Gas quality, patient preparation, facility management and equipment design parameters are intended to prevent or mitigate fire and explosion risks.
5.2	Fire alarm signal: The chamber operator should not be expected to have to contact the fire and/or emergency services manually where a situation occurs either within the chamber or its immediate vicinity.	A fire alarm and/or emergency signalling device should be provided at the operator's console for signalling a telephone operator, who is responsible for the health care facility, and/or the fire department directly. A direct alarm/monitoring system coupled to the fire department is preferable.
6	**Electrical Systems**	
6.1	Electrical regulations: Electrical wiring and equipment 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.	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.
6.2	Location of service equipment, switchboards, distribution boards & control panels: Switching of all forms of electrical power can produce sparks, containing more than sufficient energy to ignite a flammable agent.	All service equipment and high voltage (above 28 VDC) equipment should be located away from the hyperbaric chamber.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
# 2	***<u>Note 2</u>: Electrical equipment for use inside monoplace chambers, whether pressurised on air or oxygen, is restricted to communications systems and patient physiological leads only.*** <u>Warning</u>: Electrical equipment that must be installed or brought into a hyperbaric chamber should be limited to a maximum voltage rating of 28 VDC. All due and specified precautions should still be adhered to, as even low voltage switching can induce sparking with enough energy to ignite materials under normal conditions. <u>Warning</u>: These precautions should be adhered to irrespective of whether the chamber door is still to be closed, or the chamber is to be pressurised. High oxygen concentrations will remain present inside the chamber long after completion of any treatment. It is deemed to be 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). <u>Comment</u>: 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 nevertheless does provide additional guidelines and requirements for consideration where exceptions to this rule are to be considered (based on specialist and professional input, and expressed permission and acceptance by the Safety Director) as well as for installation of electrical equipment **onto** the chamber. <u>Explanation</u>: Zone 1 (EU/IEC and equivalent to ANSI/NEC Class 1 Division) implies a location in which ignitable concentrations of flammable vapours can exist under normal operating conditions or can exist frequently due to leakage. Zone 2 (EU/IEC and equivalent to ANSI/NEC 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.	
6.3	<u>Energised electrical equipment built into oxygen-piped consoles</u>: The combination of leaking oxygen piping and energised electrical equipment will produce an explosion or fire hazard.	Where control consoles contain both oxygen piping and electrical equipment, the electrical equipment should be constantly ventilated, or the enclosed space either ventilated or monitored for excessive oxygen concentrations.
6.4	<u>Location of switches, switch panels, circuit-breakers, line-fuses, relays, ballasts, motor controllers, transformers & power supplies</u>: Switching of all forms of electrical power, even low power, can produce sparks. Energy storage devices can produce sparks when switched or rapidly discharged. Sparks are a proven source of ignition.	No switching devices and no power sources should be installed within a hyperbaric chamber.
6.5	<u>Protection from water deluge</u>: Electrical equipment exposed to immersion or flooding by external sprinkler & deluge systems will fail. Patient condition and safety procedures may thereby be affected.	All critical equipment should be protected from the activation of fire water systems. Where this is not possible, safety critical equipment should be able to function long enough to allow the patients to be decompressed as may be required.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
6.6	Reserve power supplies: Where critical equipment fails due to a building or area power failure, occupants will be compromised where lighting and communications systems fail, 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 decompressed safely.	All critical equipment, including chamber lighting and emergency lighting, communications (or emergency communications, where fitted), alarm systems and detectors, fire suppression system, 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 reserve facility. Where automatic controls are used to control the chamber pressure, pressurisation and depressurisation, power to these controls should be maintained for a sufficient time to complete the treatment or at least depressurise the chamber safely. Emergency or back-up lighting to the facility should be provided.
6.7	Reserve gas supplies: Failure of compressed air systems due to a power outage and disruption of oxygen supply systems will lead to a compromised chamber environment through insufficient ventilation and create several hazards related to patient care (e.g. failure of ventilators, oxygen supply interruption, etc.).	Where only low-pressure compressors are to be used, at least one compressor should be connected to the facility emergency power system. Stored HP air supplies may be used to alleviate this situation; however, the size of the stored bank should be such that treatment can be safely concluded, without compromise to the patient's safety. Stored HP oxygen may be used as a back-up for LOX supplies.
6.8	Integrity of control & alarm systems: Power outages, especially due to spurious spikes or varying voltages, may compromise the functioning of control systems and alarms. This may lead to false alarms, loss of chamber pressure control, etc.	Chamber control and alarm systems should be so designed that hazardous conditions do not occur during power variations, interruption or restoration.
6.9	Testing: Electrical faults and failure of protective equipment rapidly reduces the safety of the operating environment.	All electrical circuits, ground fault indicators and line insulation monitors should be tested before each treatment session - to determine normal functioning and to ensure that no conductors are grounded.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
6.10	<u>Chamber wiring & equipment</u>: Monoplace chambers rely on a higher degree of prevention due to the inability to deal with electrical hazards. Inappropriate electrical wiring and unsuitable electrical equipment may present explosion, electrocution or implosion hazards in the chamber environment. Contact with "live" parts can affect the human body in the following ways: 1) Tetanization - where the affected muscles contract involuntarily, making letting go of gripped "live" part difficult. 2) Breathing arrest - where the muscles controlling the lungs contract involuntarily, altering the normal respiratory process. 3) Ventricular fibrillation - where the superposition of an external current with physiological currents leads to uncontrolled contractions and this induces alterations of the cardiac cycle. 4) Burns - caused by heating caused by the current passing through the body (Joule effect). Most standard electrical equipment is not designed to operate in or near pure oxygen environments.	**Electrical equipment for oxygen chambers shall be restricted to communications and patient physiological leads only.** Circuits shall not exceed 28 VDC and 4.0 Watts. Permanent wiring shall be protected from physical damage. Patient physiological leads shall be part of equipment compliant with this section. A range of medical monitoring devices and support equipment is available to improve the quality of care to patients. In order to provide a sound, safe basis for the application of user discretion and engineering judgement, so as to accommodate the use of some of this equipment, the following requirements and guidelines are provided (irrespective of whether the chamber door is open or not): 1) The requirements for Zone 1 locations may be followed as a general consideration for electrical wiring and equipment located inside of a chamber. However, it is not a requirement that chambers be classified as Class 1 locations. 2) NFPA 70 Article 500 provides guidance on selection of equipment and design of wiring for this class of environment. 3) Only the minimum amount of electrical equipment (restricted to physiological leads only) deemed necessary for patient care (as determined for each and every treatment) should be permitted inside the chamber. 4) All wiring intended for use within the hyperbaric chamber should be tested and approved for such use, especially in the case of oxygen chambers. 5) 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. 6) The air-chamber environment oxygen level should be continually monitored and alarms should be sounded when the oxygen percentage rises above 23.5%. 7) Advice from a competent electrical design authority should be sought to ensure compliance and safety.
6.11	<u>Insulation of conductors</u>: Non-insulated conductors introduce a source of sparking. The composition of the insulating material may present an environmental hazard when exposed to heat or fire.	All conductors used inside a chamber should be insulated using a flame resistant material. Ground conductors encapsulated within equipment do not necessarily require insulation.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
6.12	Receptacles & plugs: Interruption of any powered circuit can produce sparks sufficient to ignite a flammable agent. Non-secure and non-grounded connections are a possible source of shock and arcing.	All connection plugs and receptacles used inside the chamber should be: 1) of an approved type; 2) fitted with a locking mechanism or be supplied with a warning label against unplugging while under load; and 3) be secured and protected against accidental damage by the patient.
6.13	Internal switches: Switching is a potential source of sparking.	It is recommended that all switching be done outside the chamber, and where internal switching is necessary, this should be achieved using intrinsically safe circuitry that drives external power and control circuits. However, where necessitated, internal switches should: 1) be gas-tight; or 2) either be housed in an enclosure such that no sparks can reach the chamber atmosphere, or be rated as intrinsically safe.
6.14	Equipment temperature rating: Hot surfaces can be a primary ignition source of fires, especially within such potentially hazardous locations. The restricted space inside a monoplace chamber implies that the occupant is less able to move away from any hot surface.	No equipment installed or allowed in a hyperbaric chamber should have any exposed surfaces where the temperature exceeds 50°C. *This temperature has been based on the ignition-temperatures of materials commonly encountered inside HBO chamber environments as well as addressing the risk of thermal injury. The safety factor has been determined for fault conditions in oxygen and oxygen-enriched environments and for the protection of occupants from fire hazards.*
6.15	Exposed live electrical parts: Exposed energised electrical parts are a source of both shock and sparking due to electrical faults.	No exposed electrical parts may be present outside of approved equipment (this excludes patient monitoring leads).

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
6.16	<u>Low-voltage, low-power equipment</u>: Low voltage and low-power sources are both capable of producing both sparks and of more concern, overheating under fault conditions.	All sensors, signalling, alarm, communication and remote control equipment used or intended for use within a hyperbaric chamber should meet the following requirements: 1) equipment should be isolated from mains power either by power supply circuit design, opto-isolation or by other electronic isolation methods; 2) all leads and cables which are not enclosed within conduits should be either part of intrinsically safe equipment, or limited to less than 28 V_{dc} and 4.0 W under normal or fault conditions; and 3) the design of chamber speakers should be such that electrical circuitry and wiring are enclosed, and rating should not exceed 28 V_{rms} and 4.0 W. Alternatively, the following equipment configurations are considered acceptable: 1) Equipment listed as intrinsically safe for Zone 1, Group II. 2) Equipment that is totally enclosed and constantly purged by means of an independently supplied and discharged clean air source, which automatically de-energises when the air supply fails. 3) Equipment that is hermetically sealed, inert gas filled and positively pressurised, and is fitted with an automatic de-energization device when the initial pressure (i.e. when sealed). Changes by more than 10%. 4) Equipment approved for use by a *competent* authority and with the expressed permission of the Safety Director.
6.17	<u>Chamber grounding</u>: Inadequate grounding will compromise the effective functioning of an isolated power supply as well as any intrinsically safe equipment. Static build-up and isolated (ungrounded) metallic structures represent ignition potential in oxygen-enriched environments.	The resistance between the chamber and the ground point should not exceed 1 Ohm. Chambers should be connected to earth ground by independent, 6 AWG (copper) cables. All chamber electric equipment, as well as bunks/stretchers, should be grounded to the chamber.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
6.18	Equipment outside of chamber: Failure of critical electrical equipment due to flooding by the deluge system will compromise the safety of the chamber occupant during such emergencies.	1) All equipment that must remain functional for the safe completion of the treatment after activation of the deluge system should be adequately waterproofed. 2) Where used, conduits should be waterproof and, as applicable, be equipped with drains. 3) All electrical circuits should be protected so that flooding by water does not constitute a further hazard. 4) All electrical equipment should meet national regulations.
6.19	Residual Current Device (RCD): Electrical faults are an identified source of ignition, equipment failure and even shock.	All external chamber electrical power users, including patient support equipment, should be supplied from a RCD, a line-isolating transformer system - proving an inductive link only, as well as indicating/warning lights. (Earth-leakage protection is a practice used in some countries may fulfill the above requirements.) A secondary circuit sensing system should be used to sense single or balanced capacitive-resistive faults, as well as current leakage to ground. The sensor should be set to activate at a fault current of 30* mA within 15 mS. The full load rating of the RCD should be twice the current rating of the equipment being used. **For 110 V_{ac} systems, the fault current is to be ±75 mA, but for a 220-240 V_{ac} system, this drops to 30 mA.*
7	**Communications & Monitoring**	
# 3	Note 3: 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. Remark: "Electrical" requirements have been detailed under the previous section, par. 6, and are not repeated here. However, compliance with the electrical equipment requirements remains mandatory in order to assure the required level of safety.	
7.1	External communications equipment: Control equipment, including power amplifiers, output transformers and monitors are generally capable of producing a source of electrical discharge.	All such control equipment, should only be installed for use outside of the hyperbaric chamber.
	Internal communications equipment: The hazards associated with internally installed transducers and communications equipment have been detailed under *Low-voltage, low-power equipment*.	The requirements as detailed under *Low-voltage, low-power equipment* in section 6.15 should be complied with.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
7.2	Intercommunication: Any hazards associated with chamber operation, fire, occupant safety and medical therapy cannot effectively be avoided and controlled where a breakdown in communications between the operator and occupants occurs.	A continuous communication link between the operator and the hyperbaric chamber should be in place when in use. Communications channels are to be kept open at all times.
7.3	System components: All electrical systems present hazards associated with electrical energy discharge and patient electrocution.	All AC systems should be located outside of the chamber. Chamber communicators should have a maximum voltage rating of 28 VDC. The internal communicator should be designed for hyperbaric and high oxygen environment applications.
7.4	Entertainment systems: Television and radio circuits are potential sources of electrical energy discharge.	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 VDC, should be supplied through the RCD.
7.5	Patient monitors: Patient monitors and equipment, and the associated hazards have been addressed previously under the electrical guidelines (par. 6), as well as under the succeeding par. 8. An additional risk identified is the possibility of the patient pulling out leads.	Only low value, 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. Other monitor leads should be protected through the design of through-hull penetrations.
	Chamber atmosphere monitoring	
7.6	Oxygen: Air Chambers: Oxygen levels above 23.5% will increase flame propagation exponentially and are classified as highly dangerous. 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. Where an air chamber has not been designed to contain oxygen enriched atmospheres present, additional fire and failure risks may exist.	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%. **Air chambers not designed for oxygen enriched atmospheres should not be operated with interior levels above the safe limit of 23.5%.**
7.7	Carbon dioxide (CO_2): CO_2 levels build-up during long treatments where little or no ventilation is used. High CO_2 levels are dangerous to all occupants and potentiate oxygen toxicity. CO_2 intoxication may be insidious.	Where ventilation does not meet the rates specified in 4.3 (air) & 4.4 (oxygen) chambers, the CO_2 levels within the chamber should be monitored continuously. Visual and audible alarms should indicate CO_2 concentrations above the safe surface-equivalent- value (S.E.V.) relative to the treatment depth.
7.8	Combustible gases: Where flammable, anaesthetic gases are used within a chamber, any leak or compromised gas-discharge circuit will create an immediate explosion hazard.	Flammable gases should not to be used.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
7.9	<u>Chamber air supply monitoring</u>: Two sources of contamination exist, viz. those present in ambient air and those added by gas-compression equipment. 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. Toxic gases such as carbon monoxide (CO) will compromise the health of patients. Oil-vapour and other hydrocarbon contaminants are recognised, volatile sources of fuel in any oxygen enriched environment. Air may be provided either to pressurize the chamber (air-filled monoplace chambers) or for the air break in an oxygen-filled chamber. In both cases, oil-vapour coming into contact with oxygen is unavoidable due to the difficulty in effecting a secure and continuous seal on the patient mask.	**The use of oil-lubricated compressors is strongly discouraged**. However, where such equipment is to be used, it should be fitted with a suitable air-treatment package, capable of producing oil-free air, and the gas should be sampled (preferably continuously but at least 6-monthly) for volatilized hydrocarbons and carbon monoxide downstream of the oil filter element as may be applicable. In addition, automatic safeguards, as specified in par. 4.7, should be installed. The required minimum specification for monoplace chamber air is summarised below: Oxygen: 20% to 22% Water Vapour*: < 402 mg/m^3 (500 ppm_v or -27°C DT) Carbon Dioxide: < 500 ppm_v Carbon Monoxide: < 5 ppm_v Hydrocarbons: < 0.1 mg/m^3 (non-detectable) for liquid < 25 ppm_v (gaseous forms) Particles: < 0.5 mg/m^3 for particles > 5µ Odour: Nil* **The maximum limits for water vapour for compressed air for cylinder storage are:* *< 50 mg/m^3 (62 ppm_v) for pressures up to 20 MPa, and* *< 35 mg/m^3 (44 ppm_v) for pressures between 20 & 30 MPa.* *Air supplied to the chamber downstream of all pressure regulators need only meet the 402 mg/m^3 (500 ppm_v) requirement, except for applications where the air passes through pneumatic control computers. In these cases, a 62 ppm_v (-46°C DT) limit shall be adhere to.*

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
# 4	Note 4: Recommendation: Oxygen chambers require the use of limited quantities only of compressed air for air-breaks. The use of certified medical air, supplied in high-pressure form, will enable facilities to more easily comply with the stringent requirements for air purity for monoplace chambers. Recommendation: It is recommended that air be sampled at the compressor intake location at a time that maximum impurities are expected to be present, prior to deciding on a suitable location. At the discretion of the Safety Director, hyper-filtration systems (which ensure CO < 2 ppm_v and oil content < 0.1 mg/m^3) may replace the requirement for continuous monitoring and where replacement schedules are strictly adhered to. Periodic sampling of such air would still remain a requirement.	
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.	The Safety Director should ensure that the commercial companies supplying certified gases have an adequate quality control system. Random sampling is strongly recommended to ensure quality of supply. Piping systems used to transfer gases from commercially supplied cylinders or containers should be fitted with particulate filters of at least 66 microns or finer. (This does not replace the requirement to fit particulate filters (<10µm) at the inlet ports of the pressure regulators.)
7.11	Compressed Gas Standards: The storage and handling of compressed gases, and the installation and cleaning of oxygen and related piping systems contain fire and explosion risks.	European Compressed Gas Association (ECGA) provides minimum safety guidelines for the storage and handling of gases. CGA G-41 Cleaning Equipment for Oxygen Service provides minimum safety guidelines for the cleaning of oxygen piping systems. The 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 provide guidelines for the cleaning of oxygen piping systems.
7.12	Liquefied gases: Liquefied gases boil off rapidly and may change the composition of the chamber atmosphere.	No gases stored in a liquefied state may be taken into the hyperbaric chamber.
7.13	Visual monitoring of chamber interior: Inadequate surveillance of the chamber interior from the normal operating position will compromise the operator's response if a dangerous or emergency situation develops.	Closed circuit TV monitoring should be employed wherever direct visual monitoring from the normal operating location is not possible. This is standard industrial practice.
8	**Other Equipment and Fixtures**	
# 5	Note 5: 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. The UHMS Monoplace Hyperbaric Chamber Safety 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. However, in all cases, compliance with requirements as detailed in the rest of this document for electrical systems remains mandatory (ref. 6 above). Exceptions to the requirements should only be considered where clear expert and professional advice and endorsement is available.	

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
8.1	Non-invasive monitoring: Non-approved monitoring equipment directly affects chamber safety.	Sufficient approved brands of monitoring leads and lines are available which can be safely used within oxygen chambers.
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 hazard to the patient.	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.
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.	All IV lines should be fitted with an approved check valve (one way valve) fitted on the inside of the chamber. IV pumps should all of the positive displacement type, capable of overcoming chamber internal operating pressure.
8.4	Life-support equipment: Many standard ventilators do not provide fixed or ambient pressure-independent tidal volume. External pacemakers are not approved for use inside oxygen chambers. Insufficient infusion pump output pressure may result in inadequate infusion feed rates. Uncontrolled suction lines may be hazardous or ineffective due to changing internal chamber pressure and the resulting variable suction force available.	Ventilators designed for use within chambers are available and should be used. Pacemaker leads should be passed through chamber bulkheads using approved penetrators. Infusion pumps are located outside the chamber and should be evaluated for ability to achieve supply pressures compensating for higher internal ambient pressures. Approved penetrators should be used to pass IV lines though the chamber bulkhead. Suction lines should be fitted with control valves, and preferably, automatic sensing pressure regulators fitted. Careful monitoring by medical staff should be performed where manual control is relied on.
8.5	Patient Resting Devices: Patients with cervical spine fractures may require in-line traction.	Special trays are required to provide continuous in-line traction to patients with spinal fractures. Such trays should comply with grounding, structural, material and oxygen compatible design considerations detailed elsewhere in this document.
8.6	Approved equipment: Non-compliant and non-approved equipment, instruments and devices represent a control hazard as well as explosion, implosion and fire hazards.	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. All other equipment is expressly prohibited from being taken into the chamber. This includes any high-energy devices, photographic flash lamps, lasers and **cellular telephones**.
8.6	Permanently installed fixtures: 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.	All permanently installed fixtures should be grounded.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
	Loose fixtures and presence of ferrous materials could be the source of the build-up of a charge, or a high temperature spark cause by the percussion of oxidised ferrous metal on aluminium.	Movement of fixtures should be avoided during treatments. Metals exhibiting impact-sparking potential should not be used on high loading structures. An example would be the contact under impact of oxidised ferrous metals on aluminium surfaces that would cause high-temperature sparks. Casters and bearings should be inspected for lubrication used. Only oxygen-compatible, non-flammable lubricants may be used inside the chamber.
8.7	Conductive accessories: Conductive accessories used inside the chamber may build-up a charge.	Accessories such as belting, sheets, plastic covers, rubber accessories, etc. should be selected on the basis of reduced conductivity or antistatic properties.
8.8	Exhaust systems: Two hazards may be associated with exhaust systems, viz. noise and increased oxygen concentration at the outlet.	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. The exhaust exit points should be clearly identified and indicated with signage that prohibits smoking or any open flames in the immediate vicinity.
8.9	Direct heat sources: Open flames, smoking and heated objects represent a direct hazard to the operating environment.	All such objects, including ultraviolet sources, which may degrade acrylic viewports, should be specifically banned from the hyperbaric facility both inside, as well as in the immediate outside vicinity.
8.10	Flammable gases & liquids: Flammable gases and liquids, especially where higher concentrations of oxygen exist, represent a direct fire hazard, even after the completion of treatments.	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). Alcohol-based pharmaceuticals are only permitted where they are: medically necessary; admitted by a healthcare professional treating a specific patient; and with the specific consent of the Medical Director. The quantities of such products should be limited so that only insignificant flammable vapour would be released into the chamber environment. In addition, the oxygen monitoring requirement should be strictly adhered to and all sources of electrostatic spark discharges eliminated.
8.11	Porous materials: Materials such as wood or clothing may retain oxygen for a significant period after treatment	Non-medical, porous or open-cell materials should be excluded (or at least controlled) from being taken into the chamber.
8.12	Materials containing rubber: Rubber materials deteriorate rapidly in oxygen enriched atmospheres, leading to reduced mechanical strength.	All rubber bearing materials should be regularly tested, especially at points of kinking. This is especially applicable of rubbers containing a high carbon content.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
8.13	Defective equipment: Defective equipment may compromise safety as well as hampering emergency procedures.	Defective equipment, or equipment suspected of being defective, should be withdrawn and repaired to the satisfaction of the Safety Director prior to being taken back into the chamber.
8.14	Temperature ratings: Equipment with unsuitable temperature ratings may initiate a fire or explosion.	The temperature rating requirements of equipment should be strictly adhered to. This requires additional vigilance by all staff.
8.15	Light metals: Light metals such as cerium, magnesium and magnesium alloys are all capable of burning in air.	All combustible light metals are prohibited from being used within a hyperbaric chamber.
8.16	Radiation equipment: X-ray and gamma radiation degrade viewport acrylic materials. This is especially applicable where the source is located outside the chamber and radiography applied through the viewport. Direct sunlight is a known source of ultraviolet and infrared radiation. ASME PVHO-2 requires that any exposure to severe service environment will limit the acrylic service life.	Where viewport acrylic materials are to be exposed to any form of high-energy radiation, the service life of the windows is drastically reduced. (A three-year limit to viewport service life is generally considered appropriate in these cases.) Exposure to a severe service environment, including ultraviolet and infrared radiation, requires strict adherence to the 10-year maximum service life requirement.
9	**Maintenance**	
9.1	Regular testing & calibration: Inadequate maintenance of all oxygen handling equipment, chamber controls and safety equipment may result in equipment failure, presenting hazards to both operator and occupants.	The Safety Director should be responsible for ensuring that all equipment is regularly checked and serviced. Pressure relief valves, gauges and analysers require regular calibration.
9.2	Labelling of gas outlets: Inadequate system labelling represents an identification hazard during emergencies.	Essential controls, including gas outlets, should be clearly identified using labels. It is imperative that the gases delivered at the labelled outlet are checked prior to first use (either by review of the attached certificates of analyses, or preferably, by on-line chemical analysis).
9.3	Replacement parts: The use of non-specified spares and replacement parts may result in premature equipment failure.	The Safety Director should be responsible for ensuring that only specified components are used both during initial installation and during subsequent maintenance procedures.
9.4	Authorised work: All installation, repair and modification work to hyperbaric chambers and associated equipment directly affects the safe working function of this equipment.	The Safety Director should ensure that only competent personnel perform repair and maintenance functions, in accordance with both statutory regulations and equipment manuals. All equipment should then be fully tested and the results logged.
9.5	Maintenance logs: The lack of operating and maintenance logs prevents adequate control of maintenance procedures, resulting in premature failure of equipment.	The Safety Director should ensure that logs of both operations and maintenance procedures are maintained and correctly certified on completion thereof.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
9.6	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.	The main gas supply inlet filters should be cleaned or changed at least annually. Inlet filters for regulators, flow controls and the exhaust system similarly require annual maintenance. Manufacturers' recommendations should be adhered to at all times.

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
9.7	<u>System maintenance</u>: Inadequate and incomplete maintenance could result in 1) deterioration of systems from optimally safe readiness; and/or 2) failure of systems affecting safety during operation.	Adequate and effective system maintenance requires that several elements be addressed: 1) Competent personnel who have been appointed by the Safety Director should evaluate initial installation, repair, and modification of equipment. This evaluation should include testing under pressure. 2) The Safety Director should ensure that a comprehensive preventative maintenance system is in place, which should include: a) periodic testing of all safety related equipment - gauges, valves, meters, deluge and warning systems, etc.; b) checking of oxygen piping systems for leaks; c) checking that gas flows remain unobstructed; d) 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). e) replacement of filters, lubricants and coolants; f) checking of fluid levels; g) adjustment of regulators, sensors, safety valves and switches; h) correct and effective activation of safety systems (i.e. electrical alarms, emergency power, back-up gas supplies); i) analysis of gases; j) monitoring of viewports, pressure boundaries, calibration and statutory testing status; and k) updating logs of all periodic tests, which should be scrutinised regularly. 3) 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 Director; and regular audits by the Safety Director. 4) 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".

Ref.	Actual Determined Hazard or Risk	Minimum Requirements
9.8	<u>System cleaning procedures</u>: The lack of, ineffective, or incomplete cleaning of hyperbaric piping and gas storage systems may introduce dangerous contaminants into the system, posing toxic and/or fire hazards.	1) A cleanliness certificate after initial installation, re-erection, repair or modification to the gas supply and control system is required to be issued to the satisfaction of the Safety Director. 2) The placement of suitable filters at positions such as the oxygen or air inlet to the hyperbaric facility should be considered where appropriate. 3) Suitable cleaning procedures should be documented and should be certified as effective by the Safety Director prior to being implemented. These procedures should preferably include objective inspection and testing instructions.
# 6	<u>Note 6:</u> <u>Warning</u>: Trichloroethylene is not recommended as a cleaning compound in hyperbaric chambers. Apart from personnel hazards, the fluid reacts with carbon dioxide absorbent chemicals forming a toxic, volatile and even explosive compound.	