

RISK ASSESSMENT REPORT
FOR THE
SAN ANDRÉS HYPERBARIC CHAMBER
AMOR DE PATRIA HOSPITAL
SAN ANDRÉS ISLAND
COLOMBIA

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GENERAL

An on-site risk assessment of the hyperbaric chamber unit at the Amor de Patria Departmental Hospital, located on San Andrés Island, Colombia, was performed in response to a joint request from the unit's Medical Director and DAN America under the terms of the Recompression Chamber Assistance Program (RCAP).

This report, which documents the actual process that was followed, is intended to serve as a management review and internal audit tool, and to assure functional and personnel safety. It is not intended to suggest compliance or accreditation with any external document or authority.

The IDAN Risk Assessment Guide for Recompression Facilities was closely followed in the identification of applicable risks and as a basis for the assessment of the facility to mitigate or address these risks.

SCOPE

The risk assessment and resulting detailed report applies to a recompression facility that can be utilised for the emergency treatment of Decompression Illness (DCI) in recreational Scuba divers, as well as fishermen divers, in the diving region surrounding San Andrés.

The scope is focussed purely on the technical, operational and safety aspects related to the recompression facilities. Medical decisions, related to the treatment of injured divers, remain subject to professional medical judgement and the application of recognised therapeutic regimens, with due consideration to the availability of appropriate life support systems.

PURPOSE

The primary purpose of this report is to provide a current and documented, step-by-step assessment of the safety level of the facility, in order to provide a measure of compliance with the minimum technical safety requirements for the treatment of injured Scuba divers, as identified in the IDAN Risk Assessment Guide for Recompression Facilities (November 2010 edition).

In preparation for further safety audits and external review, this process has been 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.

It is also intended to provide guidance and recommendations for the enhancement of facility safety and improvement of certain operational aspects, as well as suggestions for possible future facility upgrades.

BASIS

The basis of the compilation of this Guide is a thorough analysis of the risks that are inherent to:

- the exposure of humans to hyperbaric pressures;
- the increased fire and explosion hazards;
- the restrictive nature of facilities;
- the multitude of mechanical and physiological hazards; as well as
- the hazards inherent in the operating of potentially dangerous machinery.

Each classified risk has been considered in the light of actual, quantifiable risks, and the facility has been assessed for compliance with specified requirements that mitigate, remove or acceptably contain such potentially hazardous situations.

BRIEF DESCRIPTION OF THE ASSESSED FACILITY

The San Andrés Hyperbaric Chamber unit comprises a 5.85 m³ twin-lock cylindrical chamber, adequately rated for 1 patient and 1 attendant. The maximum depth rating is 10 ATA (130 psi) and the chamber is pressurised using a dedicated LP air source. HP oxygen is provided for treatments. Mixed gas capabilities are not installed and the facility is fitted out with basic life support for air diving treatments. There is currently no means of fire suppression inside the chamber.

APPLICABLE STATUTORY REGULATIONS AND INTERNATIONAL GUIDELINES

The operation of pressure vessels for human occupancy, the operation of dangerous machinery and occupational health and safety, are commonly controlled by regional statutory or regulatory instruments.

Neither this guide, nor any other single international document, code of practice, or set of operating instructions, can supersede the requirement to comply with these regulations. All such statutes and referenced regulations, standards, bylaws and other regulatory instruments take legal precedence over the recommendations contained within this Guide. However, as is very often the case, many countries do not provide any form of applicable safety standards. This Guide, commissioned by International DAN (IDAN), has been specifically compiled to facilitate the assessment of a minimum level of safety for recompression facilities where safety standards are lacking, or as a supplement to local statutes and associated publications.

For reference purposes, the following documents have been consulted in the compilation of this Guide. Please note, however, that this Guide does not claim to comply either in part, or as a whole, with any or all of these documents. As the referenced documents in general apply to facilities intended for a much wider scope of services and applications, only the issues and risks relevant to facilities considered for the emergency treatment of DCI in recreational divers have been considered.

System Guidance Documents

- (1) National Fire Prevention Association (NFPA) 99, Health Care Facilities, 2005.
- (2) Undersea and Hyperbaric Medical Society (UHMS), Guidelines for Clinical Multiplace Hyperbaric Facilities 1999.

System Standards

- (1) Australian/New Zealand Standard (AS/NZS) 2299.1.2007, Occupational Diving
- (2) American Society of Mechanical Engineers (ASME) PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy, 2002.
- (3) American Society of Mechanical Engineers (ASME) PVHO-2, Safety Standard for Pressure Vessels for Human Occupancy: In-service Guidelines for PVHO Acrylic Windows, 2003.
- (4) European Standard EN 19431:2006, Pressure Vessels for Human Occupancy (PVHO) – Multiplace pressure chamber systems for hyperbaric therapy, 2006.

International Classification Society Rules

- (1) American Bureau for Shipping (ABS): Rules for Building and Classing Underwater Vehicles, Systems and Hyperbaric Facilities, 2002.
- (2) Det Norske Veritas (DNV): Rules for Certification and Verification of Diving Systems, 2004.
- (3) Germanischer Lloyd (GL): Rules for Classification and Construction, Offshore Technology, 1998.
- (4) Lloyd's Register of Shipping (LR): Rules and Regulations for the Construction and Classification of Submersibles and Diving Systems, 1991.

Additional Guidance Documents

- (1) National Fire Protection Association (NFPA) 70, National Electrical Code[®], 1999.
- (2) Compressed Gas Association (CGA), Handbook of Compressed Gases, 1999.
- (3) Compressed Gas Association (CGA), Cleaning Equipment for Oxygen Service, G-41, 1996.
- (4) American Society for Testing and Materials (ASTM), Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen Enriched Environments, G-93, 1996.
- (5) Australian Standards (AS) 4774.2, Work in Compressed Air and Hyperbaric Facilities, Part 2 Hyperbaric Oxygen Facilities, 2002.
- (6) Naval Sea Systems Command, US Navy Diving Manual, Revision 6, 2008.

Reader Note: Specific attention has been devoted to fire safety, potentially the largest and most life-threatening event related to a hyperbaric facility. Thus, as far as is practical, the NFPA Guidelines have been applied. It is of importance to note that in the USA, specifically where the NFPA 99 Standard has been adopted, there has been not a single fatality in a hyperbaric treatment facility to date. In fact, it is internationally recognised that this standard has the most effective and lasting safety record, and represents the most comprehensive fire prevention standard in existence.

EXPLANATORY NOTES

A *risk* is a state of uncertainty determined by the product of the probability of an adverse event and the severity of such an event. A *hazard* is a potentially harmful situation or agent. A *risk* results from the exposure to a *hazard*.

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

Where a number appears under the heading “*Risk Level*”, this indicates the risk level rating of the classified or identified risk. The number is allocated to provide guidance as to the importance of the issue, according to the following table:

No.	Risk Level	Requirement
1	High risk	The probability or severity of an adverse event demands compliance according to published guidelines or standards.
2	High risk	The probability or severity of an adverse event demands compliance but alternative structural or operational solutions may be acceptable. This would be at the discretion of the <i>responsible person</i> and thus allows for a degree of interpretation of choice. However, the risk should be addressed in writing.
3	Medium risk	The probability or severity of an adverse event permits conditional use of the facility with appropriate documented safety measures to manage the risk. Compliance should be effected as soon as is practically possible, for example during next planned modification, upgrading, repair or new equipment acquisition.
4	Medium risk	Compliance recommended for the optimal operation of a fully equipped facility.

The interpretation or choice allowed for under risk levels 2, 3 and 4 applies either (1) due to the type or nature of the facility; or (2) where national or local authorities may allow a degree of qualified discretion; or (3) where the *responsible person* should determine whether this is an applicable risk.

The *responsible person* referred to in this document is intended to imply either the Medical Director, or the appointed safety officer. In most countries, it is mandatory under occupational health and safety regulations to effect this appointment in writing.

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

The use of the word *specialist* in the context of this document is taken to include *competent* persons or authorities, professionally qualified experts (such as fire engineers, electrical or electronic engineers), and organisations that are recognised as specialists in a particular field.

ABBREVIATIONS

ABS	American Bureau of Shipping
ACLS	Advanced Cardiac Life Support
AHDMA	Asian Hyperbaric & Diving Medical Association
AS	Australian Standard
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BIBS	Built-In Breathing System
BLS	Basic Life Support
CGA	Compressed Gas Association
CO	Carbon monoxide
CO ₂	Carbon dioxide
DCI	Decompression Illness
DAN	Divers Alert Network
DNV	Det Norske Veritas
ECHM	European Committee for Hyperbaric Medicine
EUBS	European Undersea & Baromedical Society
GFI	Ground Fault Interrupter
GL	Germanischer Lloyd
HP	High Pressure
IDAN	International DAN
LIM	Line Isolation Monitor (also referred to as a Line Insulation Monitor)
LR	Lloyd's Register
LOX	Liquid Oxygen
LP	Low Pressure
NFPA	National Fire Protection Association
PVHO	Pressure Vessels for Human Occupancy
RCC	Recompression Chamber
SEV	Surface Equivalent Value
SPUMS	South Pacific Undersea & Medical Society
SAUHMA	Southern Africa Undersea & Hyperbaric Medical Association
TT	Treatment Table
UHMS	Undersea & Hyperbaric Medical Society
USN	United States Navy
USP	United States Pharmacopoeia

COMPLIANCE PROCESS

The following method was used to determine the degree of compliance of the facility.

The process commenced with an assessment of the applicable risks that affect a typical recompression chamber facility. The risks listed under the heading CLASSIFICATION OF RISK have been selected as applicable, or as deemed appropriate by the assessor and the responsible person. The importance of each classified risk was then rated the form of the risk level ratings indicated.

This was then followed by a detailed physical evaluation of the facility in terms of its conformance to the relevant minimum requirements provided in the Guide and a description provided to indicate compliance.

Where specialist advice suggested that exceptions to the minimum requirements contained in the Guide were acceptable, these have been documented as noted or comments in this report.

The following terms have been used for indicating compliance:

Yes	Compliant; implying either full compliance, or applicable compliance.
Noted	Compliant within the scope of the clarification notes or comments provided.
N/A	Not Applicable within the scope of this assessment or this facility, i.e. not required or not used.
N/R	Not Required as this requirement has been addressed or included elsewhere.
No	Not-Compliant
F/A	For Attention - facility has been notified and attention will be given. It remains the responsibility of the user (the Medical Director or his appointed safety officer) to follow-up and to action for rectification.

CONCLUSION

The San Andrés Chamber Unit is mechanically sound but not complete, with certain essential items of equipment not yet in place. The location is a purpose-built room inside a formal healthcare facility. There are no staff members appointed or trained as yet, although this is a project in progress.

Once fully operational, with the equipment, staffing and operational aspects attended to, the unit will be functional within the context of the community, geographical location and degree of local support and infra-structure.

With due attention paid to the issues highlighted in this report, there should be no significant reasons to doubt the safety levels, and divers should be able to receive treatments for all forms of decompression illnesses using basic oxygen tables, that are at least as safe as what the minimum industry standards demand.

The various non-compliance items are addressed within this report.

A full list of non-compliances action items and comments is provided in Appendix E.

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CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
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A. Construction and Equipment

A-1 Housing of Hyperbaric Recompression Chamber Facilities:

1. Applicable standards for all chamber facilities	1	(1) National statutory regulations, standards and local authority bylaw should be adhered to, specifically for fire safety, building and general facility aspects. Healthcare facility	Yes
	2	(2) Chapter 20 of NFPA 99, which addresses all risks on a thoroughly integrated and comprehensive basis, is specifically relevant to hyperbaric facilities and should be used for additional guidance. Alternatively, any of the following listed standards may be used: ABS, DNV, GL, LR or AS 2299.	No, F/A
2. Equipment room housing the RCC	1	The room housing the chamber should be large enough to ensure unrestricted access to all controls, viewports and piping systems.	Yes
3. Supporting foundations for the RCC	2	All supporting foundations should be strong enough to support the chamber during all intended operations, preferably including hydrostatic pressure testing. (Note: 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.) Hydrostatic pressure testing will not be possible with current location.	Yes, noted
		Ground floor location of the chamber is the preferred option.	Noted
4. Fire protection of rooms housing the chamber and ancillary equipment	1	Local and/or national regulations pertaining to such facilities should be adhered to for the chamber room, treatment areas, as well as for the ancillary equipment rooms. This should cover both fire extinguishing as well as fire-resistive construction and isolation doors. Certification of compliance should be obtained from the relevant local authority. Local regulations not clear. Extinguishers required inside chamber room. Smoke detectors should be fitted in chamber room and compressor room.	Noted, F/A
5. No smoking signs	1	No Smoking Signs should be clearly displayed both within and outside the facility and a strict "No Smoking policy" should be enforced within the unit. No smoking healthcare facility.	Yes
6. Communication	1	The facility should be linked to an emergency control centre by means of an alarm, intercommunications system or telephone. No communication devices installed. At least an alarm is required.	No, F/A
7. Lighting	1	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).	Yes

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
A-2 Fabrication of Recompression Chamber:			
1. Design of the RCC	1	During design, all aspects of chamber operation relevant to the intended application should be considered, for example internal size and layout, number of occupants, storage shelves and bracketry, and maximum working pressure. It is recommended that RCC's be rated to 50 MSW (165 FSW). Deck DDC	Yes
2. Safety standards	1	(1) Chambers should be designed to meet the requirements of any one of the internationally accepted and applicable safety standards, incorporated under the relevant national regulation, provided that the standard selected is applicable to pressure vessels for human occupancy (including in particular, requirements for the viewport design). The ASME PVHO-1 standard, which dovetails with the NFPA regulations, is the preferred standard. PVHO-1 & NB certified.	Yes
	2	(2) 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 applicable to the intended use of the chamber. Examples of such standards include AS 2299, ABS, DNV, GL and LR.	Yes
	1	(3) 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. The facility should retain a copy of the certification documents to enable appropriate regular inspections and tests to be carried out.	Yes
3. Chamber flooring	2	Flooring should be capable of supporting equipment, chamber personnel and patients for the intended operation of the chamber.	Yes
4. Flooring materials	1	(1) Flooring should be non-combustible. Aluminium	Yes
	1	(2) Non-slip surfaces should be employed.	Yes
5. Access to bilges	2	Where deck plates are fitted, adequate access to the entire bilge area should be provided for to ensure effective cleaning and disinfecting. Removable plates – corrosion evident.	Yes, F/A
6. Securing of chamber flooring	2	Where provided, flooring should be securely installed so as to prevent movement and so as to ensure electrical conductive integrity. Securing arrangements should not restrict the removal of flooring for cleaning purposes. Fasteners used.	Yes
7. Painting of chamber	4	Due care in selection of colours should be exercised. Colours providing a calming effect and enhancing internal light levels are preferred. White colour used.	Yes
8. Internal surface treatment or finish of chamber	1	The interior of the chamber may either be untreated, as in the case of stainless steel, or be treated with a non-toxic, corrosion inhibiting and low flammability paint, suitable for human occupancy and hyperbaric pressure applications.	Yes
9. Off-gassing of paint	1	No chamber should be used within the first 72 hours after application of the internal surface treatment, unless otherwise specified in the relevant material safety data information issued by the paint manufacturer.	Noted
10. Sound deadening materials	2	Where sound-deadening materials are used within the RCC, such materials should be flame resistant. Only metallic mufflers used internally.	N/A

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
11. Sufficient number of viewing & access ports for equipment	2	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. More than sufficient spare.	Yes Noted
12. Weatherproofing of electrical access ports	2	All electrical circuits should be housed in weatherproof enclosures capable of withstanding deluge from the fire protection systems, or from the weather elements if exposed. No exposure.	N/A
13. Viewport design	1 1	(1) Viewports should be designed to meet the requirements of a safety standard which makes specific provision for non-metallic, pressure bearing structures. PVHO-1 (2) 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. Dated 1985.	Yes No, F/A
14. Care of viewports	1 2	(1) Care should be exercised to ensure that correct cleaning procedures are enforced. (2) Chamber viewports should not be exposed to direct sunlight or to any direct source of heat. The ASME PVHO-2 Standard provides guidance on care and use of acrylic viewports.	Noted Yes Noted
15. Seats and bunks	2	Seats and bunks should, where-ever possible, be fabricated using non-sparking and non-combustible materials, be free of sharp edges and corners, and be designed for ease of installation and removal.	Yes
16. Pressure relief	1 2	(1) Relief valves should conform to the standard of construction and should be sized so that no situation can exist whereby gas can be introduced faster than can be discharged. No SV. (2) Relief valves should be fitted with isolating valves internally and externally to allow for shutting off in the event of malfunctioning. Valve handles should be wired in the open position using breakable safety wire.	No, F/A F/A
17. Pressure gauges	1 1 1 2 2 2	(1) All chamber compartments should be fitted with an independent pressure gauge enabling pressure to be read by external operators. This is usually achieved using control-panel mounted gauges. (2) Treatment locks should be fitted with internal caisson pressure gauges or at least a suitable means of informing the occupants of the lock pressure. Caisson gauge not yet fitted. (3) Pressure gauge lines should not supply any other devices. (4) Internal ports for gauge lines should be protected with a shield to prevent inadvertent blockages. (5) All systems should be correctly cleaned prior to use, and regularly checked for leaks. (6) Gauges should be calibrated at least once a year to ensure accuracy.	Yes Noted Yes No, F/A Noted No, F/A

A-3 Illumination:

1. Location and design of lighting	2	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 <i>competent</i> design authority as suitable for internal use, may be considered.	Yes
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CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
2. Temperature of external lighting fixtures	1	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. Canty light design.	Yes
3. Sealing materials for internal lights	1	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. Fully captured or confined sealing enclosures should be used.	N/A
4. Internally installed lights, including portable medical examination lights	1	Internally installed lighting should:	N/A
	1	(1) have an external operating surface temperature of less than 85°C;	N/A
	1	(2) be rated for a pressure of at least 1½ times the chamber maximum working pressure;	N/A
	2	(3) be located away from areas where they may be physically damaged; and	N/A
	1	(4) be designed for such applications and certified as such by a <i>competent</i> design authority.	N/A
		It is recommended that high intensity local task lighting should be provided using through-hull fibre optic devices.	Note
5. Portable medical examination lights	1	All portable lighting units should be of a self-contained, vented and shatterproof design. The design should be performed in accordance with a recognised and applicable standard, and certified as such.	N/A
6. Emergency lighting	2	(1) 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.	Noted
	2	(2) In addition, lighting power circuits should be connected to the chamber's emergency power supply.	Noted

A-4 Gas Supply Systems, Ventilation and Chamber Air Conditioning:

1. Air pressurisation system	1	(1) Air compressors and storage vessels should be designed with sufficient capacity to complete the maximum-duration medical treatment, including pressurisation, and the maximum, continuous ventilation demand. 95 cfm@10 bar	Yes
	2	(2) Compressed air systems should be fitted with after-coolers to ensure that excess condensate is removed prior to storage.	Yes
	1	(3) Inlet filters should be fitted to compressors to remove airborne particles larger than 5 microns in size.	Yes
	3	(4) It is recommended that automatic drains be fitted to all filter housings.	Yes
2. Piping systems	1	(1) Only* copper or brass alloys, or stainless steel alloys should be considered for supplies to the chamber . Exhaust system piping materials are required to be oxygen compatible, but are otherwise not restricted to the above.	Noted
	3	(2) Piping systems should be designed to deliver and maintain compression rates between the ideal of 18 MSW/min (60 FSW/min) and a minimum of 2.5 MSW/min (8 FSW/min). The industry average is 10 MSW/min (33 FSW/min).	Yes
	3	(3) Exhaust systems should be capable of surfacing the chamber from 20 MSW (65 FSW) to the surface in no more than 6 minutes.	No, noted

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	2	(4) 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.	Yes
	3	(5) All shell penetrations should be fitted with internal and external isolating valves, as close to the penetration as possible, to allow for the shutting-off of gases in the event of any malfunctioning.	Yes
	2	(6) The piping system should be configured with an "escape valve" facility, such that the occupants can override the system in the event of operator failure and return the chamber to the surface.	No, F/A
	2	(7) Chambers should only be pressurized using regulated, low pressure gas. <i>High pressure gas supplies, i.e. > 4MPa (580 psi), should be reduced as close to the source as practical.</i>	Yes
	1	(8) All pressure reducing regulators should be fitted with downstream pressure relief devices in order to protect piping and components rated for lower pressures.	N/A
	1	(9) The inlets to all pressure reducing regulators should be fitted with suitably sized particle filters (<10µm) to prevent dirt or debris from entering the sensing ports and causing downstream regulator creep.	N/A
	1	(10) 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.	N/A
	2	(11) All system components and piping should be cleaned using an approved, oxygen cleaning procedure prior to first use. * In selected cases, the use of flexible hoses is acceptable subject to all of the following criteria: (a) flexible hoses should be correctly selected for compatibility & cleanliness for the gas being transported; (b) flexible hoses should be suitably rated and appropriately certified for the system design pressure; (c) flexible hoses should be adequately protected from external damage; (d) the length of flexible hoses should be further restricted where used for high pressure gas applications; (e) provision should be made for the regular inspection of the condition of all flexible hoses.	Noted
3. Oxygen supply and exhaust system	1	The design of the supply and exhaust equipment should: (1) be capable of ensuring a supply pressure of at least 0.35 MPa (3.5 bar or 50 psi) above chamber pressure to each outlet, or as may be required by the breathing apparatus selected;	Yes
	1	(2) be fitted with emergency isolation valves, preferably fitted close to the shell;	Yes
	1	(3) ensure that sufficient capacity has been allowed for to complete treatments prior to refilling;	Note
	1	(4) ensure that high pressure supplies conform to the guidelines already provided for safe and controlled supply;	Yes
	1	(5) ensure that the exhaust system is fitted with an effective overboard dump system, which automatically adjusts to treatment pressure; and	Yes

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	3	(6) ensure that the exhaust system has been designed to restrict or control the flow between the patient and ambient pressure. In addition, a secondary (reserve) supply of oxygen should be available in the event that the main service is interrupted.	Yes Noted
4. Cryogenic supply system		Where a cryogenic supply system is installed, this should conform to local statutes, be controlled & managed by a <i>competent</i> gas supply company, and be properly maintained at least in respect of the following aspects:	
	1	(1) appropriate security of the site to prevent unauthorised access or interference;	N/A
	1	(2) routine addressing of all fire hazards, such as removal of under- or overgrowth, overhead electrical supply lines, or burnable materials (including waste matter) stored in the immediate vicinity;	N/A
	1	(3) placing and integrity of adequate warning signs and emergencies instructions;	N/A
	1	(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	N/A
	1	(5) appropriate and regular maintenance by the appointed, competent gas supply company.	N/A
5. Oxygen purity standards	1	(1) Medical oxygen requires a purity level of at least 90%. Under no circumstances should any oxygen be used other than where piped from a cryogenic source, supplied from high pressure cylinders certified as medical grade oxygen, or provided using a suitable medical oxygen generator.	Yes
	1	(2) Where a facility cannot be guaranteed of a suitably pure supply, the supply to the chamber should be analysed, either: (a) continuously when on-line, or (b) at the discretion of a <i>competent person</i> , who shall substantiate in writing the requirements for frequency of analysis, or (c) at the very least, when supplies are changed-over or refilled.	Yes, noted
6. Oxygen piping		The following minimum requirements are specified:	
	1	(1) Only <i>competent</i> and thoroughly trained persons should install, clean or work on any oxygen piping systems.	Note
	1	(2) Where copper tubing is brazed, it should be continuously purged during the brazing process with nitrogen to prevent the formation of hazardous copper oxides.	N/A
	1	(3) All oxygen supply lines should be cleaned in accordance with an approved oxygen cleaning procedure.	Note
	1	(4) Only oxygen compatible materials should be used - ASTM, CGA & ASME/PVHO publications contain lists of approved materials.	Yes
	1	(5) An oxygen shut-off valve should be installed at the point where the oxygen enters the room. Low pressure i.e. < 0.86 MPa (8.6 bar or 125 psi) may be isolated using quick acting ball valves. Quick acting valve recommended.	No, F/A

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		However, ball valves should not be used for the isolation of lines containing oxygen at pressures greater than 0.86 MPa. (Supply pressure is less than 125 psi.)	Noted
	1	(6) Oxygen supply pressure to the chamber should be visible from the control panel.	No, F/A
	1	(7) High pressure oxygen gas supplies, i.e. > 4 MPa (580 psi) should be reduced at source, or, if this is impractical, at the chamber control station.	Yes
	1	(8) All pressure reducing regulators should be fitted with downstream pressure relief devices in order to protect piping and components rated for lower pressures.	Yes
	1	(9) The inlets to all pressure reducing regulators should be fitted with suitably sized particle filters (<10µm) to prevent dirt from entering the sensing ports and causing downstream regulator creep.	No, F/A
	1	(10) 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.	Yes
	2	(11) 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.	Note
	3	(12) Only special, dedicated tools should be used for oxygen service (i.e. cleaned and non-sparking).	Note
7. Conditioning of chamber air	4	Chambers should be maintained at a temperature of below 30°C (86°F) and a relative humidity of below 65%. This may be achieved through the use of ventilation using suitably conditioned air. Alternatively, suitably-designed and approved chamber environmental conditioning units may be used. Room A/C	Yes
8. Ventilation requirements	1	(1) A minimum* ventilation rate of 85 <i>actual</i> litres per minute (3 acfm) per chamber occupant is required (<i>actual</i> flow implies the rated flow at the chamber's ambient pressure and temperature). This rate may be reduced where carbon dioxide levels are monitored continuously, or where patients are breathing oxygen using an overboard dump system, providing that oxygen levels remain below 23.5%. <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 keep oxygen levels below 23.5%.</i>	Yes
	4	(2) Stable conditions may be maintained using metabolic oxygen injection, and scrubbing to remove carbon dioxide and odour levels. Under no circumstances should the chamber interior oxygen level be allowed to exceed 23.5%.	N/A Note
9. Internal breathing apparatus	1	Each occupant should be provided with an individual breathing apparatus. The apparatus and supply system should be designed such that:	Yes
	1	(1) it is available for immediate use at all times;	Yes
	1	(2) it is independent of chamber atmosphere;	Yes

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	1	(3) it can be used simultaneously by all occupants;	Yes
	1	(4) it is fully functional at all chamber operating pressures; and	Yes
	2	(5) in the event of fire, the supply should be switched to air (or a suitable, normoxic mixture).	No, F/A
10. External self-contained breathing apparatus	2	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.	No, F/A
11. Sources of air for chambers	1	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 and building exhaust outlets.) Warning signs should be posted at the locations of such intakes. Located indoors.	Yes
12. Handling of air for chambers	2	Air supplies to the chamber should be monitored as detailed under the succeeding section on Chamber Air Supply Monitoring. Efforts should be taken to ensure that known contaminating causes are eliminated, including correct maintenance and regular inspections of compressor seals, air purification devices and compressor intakes and filters.	No, F/A
13. Use of oil-lubricated compressors	1	(1) Oil-lubricated compressors should be fitted with air-treatment packages specifically designed to produce breathing air (ref. Appendix A).	Yes
	2	(2) Air treatment packages should be fitted with automatic safeguards to ensure either that oil-contamination cannot occur, or if it does, that the air-supply system should shut down before contamination can reach the chamber.	No, F/A
14. Redundant air-supply facilities	3	(1) Air supply facilities should consist of two or more individual systems, each with sufficient capacity to maintain required flow rates on a continuous basis. This requirement may be met using one large compressor, generally of a low-pressure rating, and one standby, high-pressure compressor, used to fill an adequately sized, high-pressure storage facility. Alternatively, two low-pressure compressors; or two suitably-sized high pressure compressors; or a large supply of stored air may be considered. Single LP compressor only with no back-up available. Recommend additional system – either HP cylinders, or branch into hospital air to complete Tx.	No, F/A
	2	(2) At least one system should meet the requirements for system pressurisation and ventilation for the full duration of the intended treatment, and in the case of a standby system, the remaining duration of the longest table used for life-threatening treatments (for example, an extended USN TT 6A).	Yes
	2	(3) Each compressor should be supplied from a separate electric branch circuit. Single compressor.	N/A
15. Sound attenuation	2	(1) Mufflers should be used to reduce noise to the levels required by national regulations - typically below 85 dB (A).	Yes
	3	(2) Reverberation should be reduced by the effective use of baffling panels.	N/A
	2	(3) Where noise levels cannot be effectively reduced (such as during pressurisation), personal ear protection should be provided.	Note, F/A

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A-5 Fire Protection

1. Fire suppression system	1	(1) As a minimum, the chamber should be fitted with a portable hyperbaric fire extinguisher, rated for the maximum treatment depth.	No, F/A
	or 1	(2) An independently supplied deluge and hand-line fire suppression system is the preferred fire protection and prevention option. Not suitable for 54" chamber.	N/A
2. Unsuitable means of fire extinction	1	Fire blankets, carbon dioxide extinguishers and other devices which rely on air exclusion are either unsafe or not effective, and should not be installed in, or carried into, the chamber.	Noted
3. Fire alarm	1	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.	No, F/A

Comment: The remainder of this section is intended to apply to fire deluge systems and is provided for guidance where such systems are to be, or have been, installed. As the information is comprehensive but essentially non-mandatory as a whole, it has been included as Appendix B to this document.

A-6 Electrical Systems:

1. Electrical regulations	1	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.	Noted
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Note: In general, the only electrical circuits that should be installed inside a RCC are those for hyperbaric communications equipment and patient monitoring leads. The requirements for all other electrical devices are contained in Appendix C to this document. It is important to note that Appendix C contains mandatory requirements as well as comprehensive guidance for the selection, approval and installation of electrical devices and cabling.

A-7 Communications & Monitoring:

Warning: Ordinary communication equipment is not suitable for use within a RCC due to the potential for sparking from switches and arcing from microphones. This presents a distinct fire hazard. However, communication equipment and certain monitoring equipment are mandatory for the safe operation of the chamber, requiring special provisions to be adhered to.

Remark: "Electrical systems" requirements have been detailed under a previous section and are not repeated here. However, compliance with the electrical equipment requirements remains mandatory in order to assure the required level of safety.

Remark: The requirements for optional fire detection have been detailed under a previous section.

1. External communications equipment	1	All such control equipment should only be installed for use outside of the RCC.	Yes
2. Internal communications equipment	1	The requirements as detailed under <i>Low-voltage, low-power equipment</i> under Electrical Requirements: Appendix C on page 48 should be complied with. Amron unit.	Yes
3. Inter-communications	1	(1) A continuous communication link between the operator and all RCC locks should be in place when in use.	Yes
	3	(2) It is further recommended that: (a) a multi-channel system, with a discrete (closed circuit) operator-attendant circuits are employed (for patient sensitive issues); and	No, note
	2	(b) a sound-powered telephone or emergency communication system (e.g. surveillance microphones) is fitted.	No, note

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	1	(3) Communications channels between the locks and the control panel should be kept open at all times.	Yes
4. Patient communication systems	1	Oxygen mask or hood microphones should be approved as intrinsically safe at the rated pressure and in 100% oxygen environments.	N/A
5. Chamber atmosphere monitoring: (1) Oxygen	1	(1) Oxygen levels should be monitored at all times. Visual and audible alarms should indicate oxygen concentrations above 23.5% or below 19.5%.	No, F/A
	2	(2) Monitoring should preferably occur at two or more treatment lock locations, especially in larger chambers, with one located near the ventilation outlet or chamber exhaust point. Chambers should not be operated with interior levels above the safe limit of 23.5%.	N/A Note
<u>Comment:</u> Commercial diving operations and treatments may require oxygen percentages below 19.5%. As these treatments will only be performed under the direct supervision of a suitably qualified medical practitioner or life-support supervisor, the determination of allowable minimum levels is left to their discretion or accepted and safe diving practices.			
(2) Carbon dioxide (CO ₂)	2	Where ventilation is not (or cannot be) used, 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.	N/A
(3) Combustible gases	1	Flammable gases should not be used.	Yes
6. Chamber air supply monitoring	1	(1) All compressors should be fitted with suitable air-treatment packages capable of producing air safe for breathing purposes. In addition, automatic safeguards should be installed.	Yes, noted
	1	(2) The required minimum specification Breathing Air is detailed in Appendix A and is summarised below. Oxygen 20% to 22% Water Vapour*: < 402 mg/m ³ (500 ppm _v or dew point -27° C / -17° F) Carbon Dioxide: < 500 ppm _v Carbon Monoxide: < 10 ppm _v Hydrocarbons: < 5 mg/m ³ for liquid < 25 ppm _v for gaseous hydrocarbons (such as methane) Particles: < 5 mg/m ³ for particles > 1 µm Odour Nil	Noted
	1	(3) The required minimum specification for Medical Air, applicable for RCC's where the BIB system may be supplied with breathing air, is detailed in Appendix A and is summarised below. Oxygen 20% to 22% Water Vapour*: < 402 mg/m ³ (500 ppm _v or dew point -27° C / -17° F) Carbon Dioxide: < 500 ppm _v Carbon Monoxide: < 10 ppm _v Hydrocarbons: < 0.1 mg/m ³ (non-detectable) for liquid < 25 ppm _v for gaseous forms Particles: < 5 mg/m ³ for particles > 1µm Odour Nil	Noted

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		* In addition, the water vapour maximum limits for compressed air for cylinder storage are: < 50 mg/m ³ (62 ppm _v) for pressures up to 20 MPa (2900 psi), and at < 35 mg/m ³ (44 ppm _v) for pressures between 20 and 30 MPa (2900 – 4350 psi). Air supplied to the chamber, after any pressure reducers, need only meet the 402 mg/m ³ requirement.	
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 <i>responsible person</i> , 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. Commercially supplied gases	2	(1) The <i>responsible person</i> 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.	Noted
	2	(2) Piping systems used to transfer gases from commercially supplied cylinders should be fitted with particulate filters of at least 10 microns or finer. Particulate filters should be installed at the inlet ports of the pressure regulators.	No, F/A
8. Visual monitoring	3	Closed-circuit TV monitoring should be employed where-ever direct visual monitoring from the normal operating location is not possible. This is standard industrial practice.	No, note

A-8 Other Equipment and Fixtures:

1. Permanently installed furniture	3	All permanently installed furniture should be grounded.	Yes
2. Exhaust systems	2	(1) 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.	Yes
	2	(2) The exhaust exit point should be clearly identified and indicated with signage that prohibits smoking or any open flames in the immediate vicinity.	Noted

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B. Administrative & Maintenance:

General: *Nothing in terms of operational, administrative and maintenance activities are in place and the following section provided for guidance. Please note that all items with risk levels 1 (essential) and 2 (important) must be in place prior to operations commencing. Risk levels 3 (recommended) and 4 (good practice) to be considered as appropriate.*

B-1 Procedural Requirements:

<p><u>Explanation:</u> This section is not intended to provide exhaustive details of the administrative requirements. It is assumed that, as a minimum, RCC's will be used by suitably qualified diving personnel, responsible under their country's national regulations. However, minimum requirements are listed and some degree of guidance is offered to ensure a basic level of chamber safety.</p> <p><u>Note:</u> Clinical hyperbaric facilities are medical devices and therefore fall under the responsibility of a medical director. Diving systems fall under the occupational health and safety regulations of respective countries, requiring operation by <i>competent</i> technical staff. Military installations are often governed by a different set of regulations which may, or may not exclude any civilian liability.</p> <p><u>Recommendation:</u> 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 in the use thereof.</p>			
1. Standards	1	(1) RCC facility services that meet the needs of divers and patients, as determined by the nature of the facility, should be available to offer treatments either at all times, or within an acceptable notification period.	Note
	1	(2) Facilities should be organised, integrated, staffed and directed commensurately with the scope of services offered.	Note
	1	(3) The scope of services (medical and technical) should be clearly defined. This is essential to allow for proper transfer and referral of patients.	Note
	2	(4) Patient support capabilities (IV infusion, ventilator support, vital signs, defibrillator) should be appropriate for the level of service provided.	Note
2. Personnel	1	(1) All units should employ the services of <i>competent</i> and suitable trained staff, preferably appointed in writing, and provided with clear responsibilities and delegated with the appropriate authority.	Note
	1	(2) A registered and suitably qualified diving medical practitioner, responsible for all medical activities, or a suitably qualified designate, should be available throughout all treatments.	Note
	1	(3) In addition, a suitably qualified and appointed safety officer should be designated with the responsibility for safety.	Note
3. Responsibility	1	(1) The ultimate responsibility for the care and safety of divers and personnel lies with the owner and/or operator of the RCC facility. This person or body should thus ensure that safety, rules, practices and conduct throughout the facility are effectively and formally delegated to <i>competent</i> and <i>responsible</i> people.	Note
	1	(2) In all cases, the staff should adopt and adhere to the professional regulations pertaining to the use of such facilities as mandated by the relevant national regulations.	Note
4. Policy	1	An integrated policy, ensuring compliance with national, regional and municipal regulations, together with the all associated equipment, should be established and enforced by suitably <i>competent</i> and experienced personnel.	Note

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5. Operating procedures	1	Internationally accepted, qualified and well-proven procedures should be established, implemented and continuously monitored.	Note
6. Implementation and compliance	1	(1) The owner or user is responsible for ensuring that all such staff receive the appropriate and recognised training, adhere to operating and safety procedures, and are <i>competent</i> to fulfill their respective responsibilities effectively.	Note
	2	(2) Thorough and internationally accredited training, such as NBDHMT or UHMS recognised training courses, should be used to ensure only <i>competent</i> personnel operate the facility and equipment.	Note
	2	(3) The owner or user should ensure that periodic audits of the effective functioning of the operating and safety management systems are conducted.	Note
7. Regular operator inspections	1	A set of comprehensive pre- and post treatment check lists should be used 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.	Note
8. Patient transport/ referral	1	Procedures should be in place to transport emergency cases too and from a hospital where the RCC chamber is located outside of, or separate from a full medical facility. Self-standing or independent RCC facilities should not undertake stabilisation or extended care of emergency cases.	Note
9. Rules and regulations	1	(1) A clear set of rules and regulations for the use of the RCC facility, including the use of emergency equipment, should be established.	Note
	1	(2) All staff should be thoroughly trained in the implementation of these rules, including regular follow-up sessions, hands-on training and regular emergency and fire drills.	Note
	1	(3) Treatments should only be performed under the direct supervision of qualified personnel, with appropriate training and experience.	Note
	1	(4) The operator should remain in attendance throughout the treatment, irrespective of any emergency that may occur.	Note
	1	(5) The owner or user should ensure that discipline is maintained at all times. They are also responsible for contingency planning and training.	Note
	1	(6) All staff should be thoroughly trained and experienced in the use of emergency equipment and the following of emergency procedures.	Note
	1	(7) The owner or user should establish minimum staff qualifications, experience and complement based on the nature and size of the RCC facility, as well as the type of treatment normally provided.	Note
10. Required documentation		The following list covers the essential requirements for hyperbaric treatments:	
	1	(1) Completed indemnity form.	Note
	1	(2) RCC operator checklist.	Note
	1	(3) Patient records.	Note
	1	(4) Patient treatment log.	Note
	1	(5) Operational treatment log.	Note

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11. Training	1	(1) All staff should be thoroughly trained to the levels endorsed by national regulations and should be drilled in the appropriate operational & emergency procedures as established by the <i>responsible person</i> .	Note
	2	(2) Trainees and personnel without the requisite hours of practical experience should only operate within the facility under the direct supervision of the appropriate technician, doctor or qualified staff member.	Note
	2	(3) The responsible person, in conjunction with a medical doctor, should identify the requirements for refresher training, especially where staff are not engaged in providing treatments on a regular basis. (a) Formal qualifications, ref. B-9 below: Where not formally regulated, the frequency of refresher training should not exceed a period of 3 years. (b) Facility-specific training, including operational & emergency procedures: Refresher training frequency should be based on actual treatments performed and the holding of drills within a 12 month period. No operational member of staff should be allowed to engage in any form of treatment where they have not performed treatments or received refresher training within a maximum period of 12 months. Refresher training frequency only should not exceed a period of 2 years.	Note
12. Direct heat sources	1	All such objects, including ultraviolet sources, which may trigger the fire detection system (if fitted), or degrade acrylic viewports, should be specifically banned from the RCC facility both inside, as well as in the immediate outside vicinity.	Note
13. Flammable gases & liquids	1	(1) 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).	Note
	1	(2) 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 safety officer. 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.	Note
14. Personnel	2	(1) Nonessential personnel should be kept out of the treatment areas. People accompanying patients should be restricted to designated waiting areas.	Note
	2	(2) As a general rule, no shoes may be worn in the chamber. Where this rule must be waived, the staff should ensure that no ferrous bearing items, which may create sparks on aluminium deck plates, and appropriate shoe-covers are worn.	Note

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15. Textiles & toiletries	2	(1) Procedures should be in place to ensure that only approved garments, fabricated of 100% cotton or an antistatic blend, are worn by patients. Silk, wool and synthetic materials are specifically banned.	Note
	2	(2) Although most medical dressings do not pose a significant risk, substances such as petroleum and Velcro [®] , should be avoided.	Note
	3	(3) All garments should cover as much of the occupant's skin as is practical.	Note
	1	(4) Flammable hair sprays, hair oils, skin oils and cosmetics should be forbidden for all operating personnel as well as for patients.	Note
	2	(5) Where-ever possible, all other fabrics should be treated with flame reducing compounds or be inherently flame-resistant. It is important to note that flame reducing compounds often required regular re-application, especially after washing, and the compound manufacturer's instructions should be closely adhered to.	Note Note

Recommendations: In addition to the above requirements, the following considerations will assist in further reducing risks, the extent of possible injuries, and enabling facility staff to control the introduction of hazardous items or substances into the chamber.

- (a) Dedicated cotton garments should be supplied by the facility to patients before treatments.
- (b) Where patients are contaminated with oils or grease (such as accident victims), they should be cleaned before donning facility treatment garments.
- (c) Garments should either be supplied without pockets or pockets should be sewn up and should ideally be snug fitting cotton scrubs.
- (d) Only antistatic materials should be used.

B-2 Emergency Procedures:

1. Procedures for emergency situations	1	It is imperative that each RCC facility has a set of documented emergency procedures to ensure safe completion of treatments, safe evacuation and effective handling of each and every emergency situation. The following are included as a minimum: (a) Loss of primary air and/or oxygen supply (b) Loss of back-up air and/or oxygen supply (c) Contamination of air or oxygen supply (d) Rapid increase or decrease in chamber pressure (e) Fire inside or outside the chamber (f) Fire inside or outside of the compressor or gas storage facilities (g) Loss of power (h) Failure of any chamber systems (e.g. communications) (i) Activation of deluge system (either accidental or intentional)	Note
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2. Procedures for patient medical emergencies	1	It is imperative that each hyperbaric unit has a set of documented emergency procedures to ensure that medical emergencies can be managed appropriately. The following are included as a minimum: (a) Oxygen toxicity (b) Arrhythmias, cardiac arrest (& defibrillation) (c) Pneumothorax (d) Barotrauma (middle ears, sinuses, teeth, lungs, intestinal) (e) Emergency myringotomy (f) Arterial gas embolism (g) Respiratory distress / bronchospasm (h) Suspected hypoglycaemia (i) Vomiting (j) Loss of consciousness (k) Claustrophobia (l) Uncooperative / aggressive patients.	Note
3. Procedures for medical emergencies in staff	1	It is imperative that each hyperbaric unit has a set of documented emergency procedures to ensure that staff emergencies can be managed appropriately. Some “patient-procedures” will also apply to staff, but dedicated procedures should be available for: (a) Sharps injury/infective fluid exposure (b) Decompression illness	Note

B-3 Equipment:

1. Approved equipment	1	(1) Only equipment that is specifically compliant with the requirements of this document, or that has been specifically approved for use within RCC's, should be used.	Note
	1	(2) All other equipment is expressly prohibited from being taken into the chamber. This includes any high energy devices, photographic flash-lamps and lasers.	Note
2. Defective equipment	1	Defective equipment, or equipment suspected of being defective, should be withdrawn and repaired to the satisfaction of the delegated safety officer prior to being returned to the chamber.	Note
3. Flammable items	1	These items should be kept to an absolute minimum inside the RCC. Newspaper is expressly prohibited, due to volatile ink used in some cases.	Note
4. Temperature ratings	1	The temperature rating requirements of equipment should be strictly adhered to. This requires additional vigilance by all staff.	Note
5. Oxygen equipment compatibility	1	(1) Only approved, dedicated oxygen containers, control mechanisms, interconnecting hoses and fittings, valve-seat materials and lubricants should be used.	Note
	1	(2) International guides for determining the suitability of materials for oxygen compatibility should be adhered to.	Note
	1	(3) Static conditions and impact conditions are both applicable. ASTM and NFPA guidelines for design using oxygen compatible materials should be followed.	Note
6. Oxygen cleaning	1	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.	Note
7. Oxygen lubricants	1	Only oxygen compatible lubricants should be used inside the RCC.	Note

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[®].

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8. Light metals	1	All combustible light metals (such as magnesium) are prohibited from being used within a RCC.	Note
9. Radiation equipment	1	Radiation sources can ignite hydrocarbon-based flammable gases with a concentration above 1000 ppm _v . Where the use of such equipment is deemed absolutely necessary, a hydrocarbon detector should be installed, and where flammable gases are detected, the equipment should not be operated until the chamber atmosphere has been cleared.	Note
10. Radiation exposure	1	Where viewport acrylic materials are to be exposed to any form of high-energy radiation, the safe service-life of the windows is drastically reduced. Exposure to X-ray or Gamma radiation reduces viewport service life to three-years. Ultraviolet and infrared radiation exposure (such as from direct sun-light) implies a severe service environment as per ASME PVHO-2 and requires strict adherence to the 10 year maximum service life requirement.	Note Note Note

B-4 Handling of Gases:

1. Compressed gas standards	2	(1) CGA Handbook of Compressed Gases provides minimum safety guidelines and the relevant sections should be complied with for the storage and handling of all gases (e.g. compressed air, oxygen, nitrogen) used within the facility.	Note
	1	(2) CGA G-41 Cleaning Equipment for Oxygen Service provides minimum safety guidelines for the cleaning of oxygen piping systems. Either this reference work, or a suitable alternative as may be deemed appropriate by the <i>responsible person</i> , should be adhered to in full.	Note
	2	(3) ASTM G-93 Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen Enriched Environments provides further guidelines for the cleaning of oxygen piping systems.	Note
2. Procedures for handling gases	1	Only qualified staff should be permitted to operate or work on gas handling equipment.	Note
3. Liquefied gases	1	No gases stored in a liquified state should be taken into the RCC.	Note
4. Flammable gases	1	No flammable gases should be stored in or near the RCC facility, or near the compressor intake(s).	Note
5. Stored gases	1	(1) The amount of oxygen stored in or around the RCC facility should be kept to the minimum required to complete treatments, or to deal with emergency situations.	Note
	1	(2) Pressurised containers may only be introduced into the RCC where they are approved for use, such as emergency gas supplies.	Note
6. Non-flammable gases	1	All non-flammable gases required for use may be piped into the facility. Shut-off valves accessible to personnel should be provided at the points of entry to the room housing the chamber.	Note

B-5 Maintenance:

1. Regular testing and calibration	2	(1) The appointed safety officer should be responsible for ensuring that all equipment is regularly checked and serviced.	Note
	2	(2) Pressure relief valves, gauges and analysers require regular calibration.	Note

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2. Labelling of gas outlets	2	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 (by review of the attached certificates of analyses, or preferably, by on-line chemical analysis).	Note
3. Replacement parts	2	The safety officer should be responsible for ensuring that only specified components are used both during initial installation as well as during subsequent maintenance procedures.	Note
4. Authorised work	2	(1) The safety officer should ensure that only <i>competent</i> personnel perform repair and maintenance functions, within the requirements of both the statutory regulations and the equipment manuals.	Note
	2	(2) All equipment should then be fully tested and the results logged.	Note
5. Maintenance logs	1	The safety officer should ensure that logs of both operations and maintenance procedures are maintained and correctly certified on completion thereof.	Note
6. System maintenance		Adequate and effective system maintenance requires that several elements be addressed:	Note
	1	(1) Initial installation, repairs, additions and modifications of equipment should be evaluated by <i>competent</i> personnel who have been appointed by the safety officer. This evaluation should include testing under pressure.	Note
	2	(2) The safety officer 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 (lubricants, coolants, etc.); (g) adjustment of regulators, sensors, safety valves and switches; (h) correct and effective activation of safety systems (i.e. deluge system, 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 (l) scrutinised regularly	Note
3	(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 officer; and regular audits by the safety officer.	Note	

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	4	(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".	Note
7. System cleaning procedures	2	(1) A cleanliness certificate after initial installation, re-erection, repair or modification to any of the gas supply and control systems should be issued to the satisfaction of the safety officer.	Note
	2	(2) The placement of suitable filters at positions such as the oxygen or air inlet to the RCC facility, should be considered where appropriate.	Note
	2	(3) 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.	Note
	2	(4) A suitable, non-corrosive, antiseptic and detergent should be used to clean all surfaces following each treatment day.	Note
	1	(5) Due caution is required in cleaning certain components, e.g. viewports, fire-treated bedding and mattresses, to avoid degradation or a reduction in fire-resistant properties.	Note
	2	(6) Safe and comprehensive 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.	Note
Warning: Trichloroethylene is not recommended as a cleaning compound in RCC's. Apart from personnel hazards, the fluid reacts with carbon dioxide absorbent chemicals forming a toxic and explosive volatile compound.			
8. Approved lubricants and consumable materials	1	(1) The acceptance criteria for hyperbaric-approved materials should include the following: (a) suitably pressure rated oxygen compatibility, (b) non-toxic, (c) non-reactive with system elastomers and other materials, (d) non-corrosive, (e) effective and easy to apply/use.	Note
	2	(2) Materials should be clearly identified for use and should be packaged to keep out contaminants.	Note
	2	(3) Lubricants should be used sparingly and may not be used to correct equipment flaws (such as non-sealing joining surfaces or compensating for poor fits). All excesses should be removed prior to equipment use.	Note

B-6 Electrical Safeguards:

1. Testing	1	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.	Note
2. De-energization of equipment	1	All non-life critical equipment within a RCC should be de-energized prior to commencement of the deluge, unless adequately waterproofed.	Note

B-7 General Safeguards:

1. Furniture	2	(1) Periodic inspection of the integrity of joints, grounding and insulation by foreign materials should be conducted.	Note
	2	(2) Moving of furniture inside the chamber should be avoided during treatments.	Note

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	2	(3) Metals exhibiting impact sparking potential should not be used on leg tips or other high loading structures. An example would be the contact under impact of oxidised ferrous metals (e.g. chair-leg tips) on aluminium surfaces (as commonly used for deck-plates) which would cause high-temperature sparks.	Note
	2	(4) Casters and bearings should be inspected for lubrication used. Only oxygen-compatible, non-flammable lubricants may be used inside the chamber.	Note
2. Materials containing rubber	2	All rubber bearing materials should be regularly tested, in accordance with the established periodic maintenance requirements, especially at points of kinking. This is especially applicable of rubbers containing high carbon content.	Note
3. Fire protection equipment	1	(1) All controls including switches, valves and monitoring equipment should be visually inspected prior to each and every treatment session.	Note
	1	(2) Semi-annual inspections of extinguishing media and full system functioning should be conducted.	Note

B-8 House-keeping:

1. Tidiness	1	The owner or user should ensure that staff keep all operating areas free of unnecessary equipment, that non-essential equipment is stowed away and that essential equipment is on-hand.	Note
2. Cleanliness	1	(1) It is essential that the RCC be kept meticulously free of all greases, lint, dirt, dust and unwanted materials.	Note
	1	(2) The person tasked with this daily function should be thoroughly briefed as to the dangers to occupants under normal operating conditions.	Note

B-9 Medical Staff Training, Qualifications & Registrations:

1. Diving medical practitioner	1	The diving medical practitioner should hold the following minimum qualifications and registration: (a) Registration within national regulations as a medical practitioner. (b) Diving medicine training as endorsed by national regulations or by one of the recognised international hyperbaric and/or diving medical associations. (c) Current BLS training (ACLS training recommended). (d) Be declared medically fit to enter the chamber while under pressure.	Note
2. Chamber operators	1	The person operating the hyperbaric chamber should be a suitably qualified chamber operator with appropriate training as endorsed through national regulations or by one of the international hyperbaric and/or diving medical associations.	Note
3. Chamber attendants	1	The person(s) attending to patients inside the chamber should be suitably qualified to administer relevant functions with: (a) Appropriate training as endorsed through national regulations or by one of the international hyperbaric and/or diving medical associations. (b) Current BLS training. (c) Be declared medically fit to enter the chamber while under pressure.	Note

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
B-10 Patient Care:			
1. Staffing levels	1	The following minimum staffing levels should be maintained at all times: (a) The chamber operator (b) At least one chamber attendant (c) The HBO medical practitioner	Note
2. Medical supervision	1	A qualified diving medical practitioner should be available at all times during treatment for supervision of the treatments, in line with international requirements for medical supervision.	Note
3. Patient medical screening	1	Each and every patient should be screened by a qualified diving medical practitioner prior to admission for treatment. This includes confirming appropriateness of treatment, excluding contra-indications and assessing the patient's physical and psychological needs.	Note
4. Patient orientation	2	Patients should receive an orientation to the facility, patient policies and procedures prior to commencing with treatment. This should include safety precautions specifically related to fire and pressure hazards (prohibited items and materials).	Note
5. Patient records & procedures	1	Patient medical records should be kept up-to-date and confidential, individual files kept available for each patient. The guidelines issued by the national healthcare professional legislation should be adhered to.	Note
6. Minimum medical emergency equipment available	2	Medical equipment that can cope with foreseeable emergencies, consistent with the advertised scope of services, should be available, maintained and secured in the treatment facility.	Note

APPENDIX A

GUIDANCE ON CHAMBER AIR SPECIFICATIONS

Introduction

Confusion exists over the so-called minimum specifications for breathing air. This is partly due to the fact that breathing air is often stored in high pressure form, requiring additional corrosion considerations and therefore mandating uncomfortably dry air. However, the major debate centres around the safety aspects regarding the presence of hydrocarbons and the definition of *oil-free* air.

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

The NFPA 99 standard has accounted for the requirements for air that is both oxygen-compatible and medically safe. The resultant standard is classified as Medical Air (as per USP), together with additional restrictions.

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

The following two specifications both allow a greater amount of water vapour to be present (based on the many international diving standards for surface-supplied air) for air up to 3.5 MPa (500 psi). It is important, however, to note the additional requirements for air compressed to higher pressures, required to avoid the risk of regulator “freeze-up”.

Breathing Air Specification

The required minimum specification for breathing air, where the intended application excludes any mixing to achieve oxygen enrichment above 23.5% and where the air is not intended to be piped into any system that may be used for the conveyance of oxygen enriched mixtures, or pure oxygen (such as for the BIBS):

Oxygen: 20% to 22%

Water Vapour: Less than 402 mg/m³ (500 ppm_v or dew point -27° C / -17° F).

Compressed air for cylinder storage should meet the requirement of 50 mg/m³ (62 ppm_v or dew point -46° C / -51° F) for pressures to 20 MPa (2900 psi), and 35 mg/m³ (44 ppm_v) for pressures between 20 and 30 MPa: (2900 and 4350 psi).

However, air supplied to the chamber, downstream of all pressure regulators, need only meet the 402 mg/m³ requirement.

Carbon Dioxide: CO₂ less than 500 ppm_v

Carbon Monoxide: CO less than 10 ppm_v

Oil content: Less than 5 mg/m³ as a liquid.

Liquid oil content is defined as a level of condensed hydrocarbons, measured in mg/m³ at normal temperature and pressure.

Where oil-lubricated compressors are used, irrespective of the filtration system employed, the incoming chamber air supply should be continuously monitored downstream of the filters for oil content.

Gaseous hydrocarbons (for example methane) are to be less than 25 ppm_v

Odour: Nil

Particles content: The concentration of particles should be less than 5 mg/m³ for particles greater than 1 micron in size.

Medical Air Specification

The required minimum specification for medical air, where the intended application is for medical hyperbaric oxygen therapy, or where the application includes mixing to achieve oxygen enrichment above 23.5%, or where the air is intended to be piped into any system that may be used for the conveyance of oxygen-enriched mixtures, or pure oxygen (such as for the BIBS):

Oxygen: 20% to 22%

Water Vapour: Less than 402 mg/m³ (500 ppm_v or dew point -27°C / -17° F).

Compressed air for cylinder storage should meet the requirement of 50 mg/m³ (62 ppm_v or dew point - 46°C / - 51 °F) for pressures to 20 MPa (2900 psi), and 35 mg/m³ (44 ppm_v) for pressures between 20 and 30 MPa (2900 and 4350 psi).

However, air supplied to the chamber, downstream of all pressure regulators, need only meet the 402 mg/m³ requirement.

Carbon Dioxide: CO₂ less than 500 ppm_v

Carbon Monoxide: CO less than 10 ppm_v

Oil content: As a *liquid*, oil should be non-detectable. Liquid oil content is defined as a level of condensed hydrocarbons, measured in mg/m³ at normal temperature and pressure. The lowest detectable level is 0.1 mg/m³. 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.

Gaseous hydrocarbons (for example methane) are to be less than 25 ppm_v

Odour: Nil

Particles content: The concentration of particles should be less than 5 mg/m³ for particles greater than 1 micron in size.

APPENDIX B

GUIDANCE ON CHAMBER FIRE DELUGE SYSTEMS

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
<p><u>Comment:</u> While it is mandatory for medical hyperbaric chamber facilities to have both a hand-line and a deluge system, the deluge system may be manually and/or automatically activated, as determined by the medical director and/or the <i>responsible person</i>. Due consideration should be paid to the type of medical procedures to be conducted and the resultant implicit dangers to the patient in the event of an accidental triggering of the automatic system. Also, excluding oxygen-compounded fires, most fires within a chamber can be effectively extinguished using a manual hand-line. However, reaction times based on physical layout and access; limited chamber size - potentially giving rise to rapid oxygen-enrichment in the event of a leak; response time of oxygen monitoring systems; and the possibility of potentially hazardous equipment being required for use within the chamber (e.g. a defibrillator), all affect the decision to select an automatic activation system.</p> <p>This chamber is really too small to consider a deluge system. However, the requirements are left in place for future guidance – should a larger chamber be considered.</p>			
1. Component failure	1	The design of the system should be such that failure of components in either the deluge or the hand-line systems will not compromise the effective functioning of the other system.	Note
2. Automatic activation of functions	1	On activation of either the deluge or hand-line suppression systems, the following should occur automatically:	Note
	2	(1) visual and audio indication of an alarm situation at the operator's console, with signalling to the facility fire centre;	Note
	2	(2) disconnection of all ungrounded electrical power systems, excluding those that are intrinsically safe;	Note
	2	(3) isolation of all oxygen supplies to the chamber interior and activation of oil-free breathing air supply (or normoxic gas) in the place of oxygen;	Note
	1	(4) emergency lighting and communication, where applicable;	Note
	1	(5) any special activities conducted within the chamber which may be required to occur automatically or simultaneously.	Note
3. Fire alarm signal	1	A fire alarm and/or emergency signalling device should be provided at the operator's console for signalling either a telephone operator, who is responsible for the health care facility, or the fire department directly. A direct alarm/monitoring system coupled to fire department is preferable.	Note
4. Fire suppression system power supply	1	All fire suppression system components and controls should be powered from the RCC facility's emergency power system, or preferably from the chamber's independent back-up power reserve.	Note
5. Water deluge system	1	(1) A fixed water deluge system should be installed in all manned locks, excluding locks used solely for transfer purposes.	Note
	1	(2) The system should be designed so as to function effectively and simultaneously in all treatment locks, irrespective of where different pressures may exist.	Note
	1	(3) The system should perform as specified across the full operating pressure range of the chamber.	Note
	2	(4) A suitable water filter (strainer) should be installed at the outlet of the water supply system.	Note

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
6. Location of activation controls	2	(1) Activation and de-activation controls should be installed at the operator's console and inside each manned lock. The number and location of control stations required inside each lock is dependant on the lock size and is subject to the <i>responsible person's</i> discretion.	Note
	2	(2) All controls should be designed to prevent inadvertent activation, but without causing a delay where activation is required.	Note
7. Deluge activation time	1	Deluge valves should open within 1 second of the activation signal. Water should be delivered from the sprinkler heads no longer than 3 seconds after the activation signal.	Note
8. Deluge system coverage (Refer to notes below.)	1	(1) The system should be designed so that the number and positioning of the sprinkler heads achieve:	Note
	2	(a) a uniform spray coverage;	Note
	2	(b) an <i>average</i> spray density at <i>floor level</i> of no less than 82 litres per minute per square metre (2 gallons per minute per square foot);	Note
	2	(c) an actual coverage of no less than 41 litres per minute over any floor area larger than 1 square metre (1 gallon per minute per square foot).	Note
	1	(2) The design should account for the fact that increased air density in the hyperbaric atmosphere causes increased resistance to water droplet movement, which in turn causes a reduction in spray angles (necessitating a greater number of sprinkler heads).	Note
1	(3) The system should be tested on completion of installation, or after system modifications, preferably across the full range of operating pressures, and the effective functioning and design parameters confirmed.	Note	
<p>Definition: Floor level in a horizontal, cylindrical chamber is taken to mean the level at ¼ diameter below the chamber centre-line, or actual floor level, whichever gives the greater area.</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 RCC facilities providing regular hyperbaric oxygen treatments.</p> <p>Comment: Recent research into high-energy absorbing, fogging-based deluge systems indicates that these systems may be more suited to hyperbaric oxygen treatment facilities.</p>			
9. Deluge system water capacity	2	(1) The system should be designed with sufficient water capacity to maintain the required flow, as determined by the average rate of 82 litres per minute multiplied by the actual floor in square metres (2 gallons per minute per square foot) in each chamber lock for at least 1 minute.	Note
	2	(2) The maximum water capacity should be determined by the bilge capacity or drainage system, so as not to allow flooding of equipment, or in extreme cases, drowning of patients who may have fallen to the floor.	Note
10. Reserve supply pressure	1	The deluge system should have sufficient stored pressure to operate for a minimum period of 15 seconds without electrical power.	Note

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
11. Hand-line extinguishing systems	2	(1) Each treatment lock should be fitted with at least two hand-lines.	Note
	1	(2) Where the treatment lock is designed for two patients or less, and a single hand-line only is fitted, the hand-line should reach the entire interior of the chamber safely, including the bilge as applicable.	Note
	1	(3) Each transfer lock should be fitted with at least one hand-line (or at least a hyperbaric fire extinguisher).	Note
	1	(4) Where bilge access panels are installed, at least one hand-line should be long enough to be used to extinguish fires in the bilge area.	Note
12. Minimum criteria of hand-lines	2	(1) Hand-lines should have a 12 mm (½") minimum internal bore.	Note
	1	(2) All hand-lines should have a rated working pressure greater than the designed pressure of the supply system.	Note
13. Activation of hand-lines	1	Hand-lines should be activated using individual, quick-opening valves located within each chamber lock.	Note
14. Dual valves	1	All hand-lines should be fitted with individual override valves, placed in accessible locations outside the chamber and sealed in the open position with frangible safety wire seals.	Note
15. Water supply pressure and flow	1	(1) The hand-line water supply pressure should be at least 0.35 MPa (50 psi) above chamber pressure at all times.	Note
	2	(2) The system should be capable of delivering at least 19 litres per minute (5 gallons per minute) per hand-line at maximum chamber pressure.	Note
16. Optional automatic fire detection	4	Where fitted, automatic fire detectors should conform to the following:	
	2	(1) Surveillance detectors which respond to flame radiation within 1 second of flame origination should be employed.	Note
	2	(2) The number and physical location of detectors should be dependent on the sensitivity of each detector and on the configuration of the spaces to be protected. Blind spots are to be eliminated.	Note
	1	(3) The detection system should be powered from the chamber facility back-up system, or be fitted with an independent back-up battery.	Note
	2	(4) Where used to activate the deluge system automatically, the requirements for manual activation and deactivation, as well as the required response time, should still apply.	Note
	2	(5) The system should be designed with self-monitoring functions for fault detection, as well as fault alarms and indicators.	Note
17. Regular function testing	1	(1) Deluge and hand-line systems should be function tested at least every 6 months and full effective function confirmed.	Note
	2	(2) Where bypass systems are installed, the design of the system test mode should be such that the system resorts to normal operating mode by default after the test. This requirement does not replace or cover the need for full function and performance testing after initial installation or any subsequent system modifications.	Note

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
<p><u>Recommendation:</u> Bypass systems encourage regular testing as the interior of the chamber need not be deluged. However, due care should be exercised in the selection of a bypass system, such that potency of the full flow path can be assessed. Lines may become blocked with time, reducing the supply of water to the individual sprinkler heads. It may be preferable to design the bypass such that full flow is physically achieved, with the water being captured by means of a set of flexible pipes led down to the bilge (and preferably into suitable containers). It would remain advisable to measure flow (time and volume) to ensure that full design flow is achieved – a minimum activation time would depend on the design, but usually no less than 15 seconds.</p>			

APPENDIX C

ELECTRICAL REQUIREMENTS FOR RECOMPRESSION FACILITY INSTALLATIONS

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
<p>Warning: Electrical equipment that must be installed or brought into a RCC should be limited to a maximum voltage rating of 24 to 28 V_{DC}. 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.</p> <p>Definition: 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.</p> <p>Explanation: A hyperbaric chamber environment is not classed as a Class 1 location because of oxygen-enriched concentrations. It is the 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), that necessitates the specification of Class 1 requirements for the electrical systems, which potentially contain high-energy ignition sources.</p>			
1. Service equipment, switchboards, distribution boards & control panels.	1	All service equipment and high voltage (28 V _{DC} ⁺) equipment should be located outside of the chamber.	Yes
2. Energised electrical equipment built into oxygen piped consoles	2	Where control consoles contain both oxygen piping and electrical equipment, the electrical equipment should be totally enclosed or constantly ventilated, or the enclosed console space either ventilated or monitored for excessive oxygen concentrations. Open control panel arrangement.	N/A
3. Switches, circuit-breakers, line-fuses, relays, ballasts, motor controllers, transformers & power supplies	1	(1) No switching devices and no power sources should be installed within a RCC.	Yes
	1	(2) Non-fixed items of equipment may only be used inside a chamber where certified as intrinsically safe, or where assessed as safe by the <i>responsible person</i> .	Note
4. Electric motors	2	Fan-motors should be mounted outside of RCC's. However, motors specifically designed and certified for use within hyperbaric atmospheres may be considered (e.g. for CO ₂ scrubbers and NIBP monitors), with the written acceptance of the safety officer. Acceptable motors include explosion-proof motors, purged or gas-filled motors and motors that can be demonstrated to be localised heat-source-free and arc-free.	N/A
5. Protection from water deluge	1	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.	N/A
6. Reserve power supplies	2	(1) 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 healthcare facility's emergency electrical system, or preferably, an independent reserve facility.	Yes

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	1	(2) 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. Alternately, full manual controls should be provided.	N/A
	2	(3) Emergency or back-up lighting to the facility should be provided.	Note
7. Reserve gas supplies	2	(1) Where only low-pressure compressors are to be used, at least one compressor should be connected to an emergency power system.	Note
	2	(2) 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 occupants' safety.	N/A
	2	(3) Stored HP oxygen may be used as a back-up for LOX supplies.	Yes
8. Integrity of control and alarm systems	1	Chamber control and alarm systems should be so designed that hazardous conditions do not occur during power variations, interruption or restoration.	N/A
9. Chamber wiring and equipment	1	(1) The requirements for Class 1, Division 2 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.	Noted
	2	(2) NFPA 70 Article 500 provides guidance on selection of equipment and design of wiring for this class of environment.	Noted
	1	(3) Only the minimum amount of electrical equipment deemed necessary for patient care (as determined for each and every treatment) should be permitted inside the chamber. The chamber should not be used to store electrical equipment not required during the treatment.	Yes
	1	(4) All equipment intended for use within the RCC should be tested and approved for such use.	Yes
	1	(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 <i>competent</i> authority.	N/A
	1	(6) The chamber environment oxygen level should be continually monitored and alarms should be sounded when the oxygen percentage rises above 23.5%.	No, F/A
	2	(7) Advice from a <i>competent</i> electrical design authority should be sought to ensure compliance and safety.	Note
10. Insulation of conductors	1	(1) All conductors used inside a chamber should be insulated using a flame resistant material.	Yes
	1	(2) Ground conductors encapsulated within equipment, or wiring forming an integral part of approved equipment, do not require insulation.	N/A
	2	(3) Wiring forming an integral part of equipment approved for use inside the chamber does not need to meet the flame resistance classification.	N/A
11. Wiring methods	1	(1) Fixed wiring should comply with the requirements of Class 1 Division 2.	Yes
	2	(2) Wiring classified as intrinsically safe should be permitted using methods for conventional locations.	N/A

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	2	(3) Where fixed conduits, boxes and enclosures are used, these should be approved as explosion proof for Class 1 Division 1 locations.	N/A
	1	(4) Decisions on the suitability of wiring methods should be taken by a person <i>competent</i> to do so.	Noted
12. Sealing and drainage of conduits and enclosures.	2	Requirements and guidance on sealing and drainage are provided for in NFPA 70, Article 501-5 and should be complied with.	N/A
13. Flexible cords used for portable equipment	1	Only cords which are:	N/A
	2	(1) of a type approved for extra-hard utilisation;	N/A
	1	(2) include a ground conductor;	N/A
	1	(3) are connected to terminals in a secure and approved manner; and	N/A
	1	(4) are supported in such a manner that no tension exists on the terminal connections; should be used.	N/A
	2	The exception to these rules are cords normally supplied with portable devices, rated for less than 2A, and where the cord is securely fastened and protected from accidental damage. In addition, the device should have an on-off power switch and the plug of the cord should not be used to interrupt power.	N/A
14. Receptacles and plugs	1	All connection plugs and receptacles should be:	N/A
	2	(1) of an approved type;	N/A
	1	(2) grounded via a grounding conductor;	N/A
	1	(3) fitted with an interlocking mechanism to prevent withdrawal or insertion while energised;	N/A
	1	(4) fitted with a locking mechanism or be supplied with a warning label against unplugging while under load; and	N/A
	2	(5) be secured and protected against accidental damage by occupants.	N/A
15. Internal switches		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 which drives external power and control circuits. However, where necessitated, internal switches should:	Note
	1	(1) be waterproof; or	N/A
	1	(2) either be housed in an enclosure such that no sparks can reach the chamber atmosphere, or be rated as intrinsically safe.	N/A
16. Equipment temperature rating	1	No equipment installed or allowed in a RCC should have any exposed surfaces where the temperature exceeds 85°C (185°F).	Yes
17. Exposed live electrical parts	1	No exposed electrical parts may be present unless certified as intrinsically safe (this excludes patient monitoring leads).	N/A
18. Low-voltage, low-power equipment	1	All sensors, signalling, alarm, communication and remote control equipment used or intended for use within a RCC 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;	Yes

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	1	(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 0.5 A under normal or fault conditions;	Yes
	1	(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 25 W; and	Yes
	1	(4) battery operated devices should meet the requirements as stipulated below.	N/A
19. Patient care devices		In addition to the limitations of surface temperature, i.e. less than 85°C (185°F), operating voltage (28 V _{DC} or less) and adequate certification and/or testing for use within RCC chambers, the following minimum requirements should be met:	
	2	(1) patient care devices should be designed and certified as safe for patient care applications (e.g. as per NFPA 99 Chpt 9);	N/A
	1	(2) the electrical and mechanical integrity should be continuously monitored under the facility maintenance program;	N/A
	1	(3) devices utilizing oxygen should be designed so that oxygen cannot accumulate in the electrical sections under any conditions;	N/A
	1	(4) the charging of batteries should only be permitted where battery enclosures are used, overcharging is specifically protected, batteries cannot off-gas or build up excessive heat, and the risk of short-circuiting is precluded; and	N/A
	1	(5) the devices have been successfully tested for proper performance over the full operating pressure range.	N/A
20. Portable & battery-operated electrical or electronic equipment		All such equipment, including permanently installed sensors, communications devices, signalling, alarm or remote control equipment should meet the following criteria:	
	1	(1) batteries should be fully enclosed and secured within the equipment enclosure;	N/A
	1	(2) batteries should be suitable for chamber maximum operating pressure, and be of a sealed type that does not off-gas during normal use;	N/A
	2	(3) batteries should not be charged while located inside the chamber;	N/A
	2	(4) batteries should not be changed whilst the equipment is located inside the chamber;	N/A
	1	(5) Lithium-Ion batteries are specifically excluded; and	N/A
	1	(6) the equipment electrical rating should not exceed 28 V _{dc} and 25 W, or 12 V _{dc} and 48 W.	N/A
		Alternatively, the following equipment configurations are considered acceptable:	N/A
	1	(1) Equipment listed as intrinsically safe for Class 1, Division 1, Group B.	N/A
	1	(2) Equipment which is totally enclosed and constantly purged by means of an independently supplied, oxygen-compatible air-source, which automatically de-energises when the air supply fails.	N/A
	1	(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%.	N/A

CLASSIFICATION OF RISK	RISK LEVEL	MINIMUM REQUIREMENT	CONFORMS
	1	(4) Equipment approved for use by a <i>competent</i> authority and with the written permission of the safety officer.	N/A
21. Chamber grounding	1	The resistance between the chamber and the ground point should not exceed 1 Ohm.	No, F/A
22. Line isolation monitoring	2	All chamber internal electrical circuits should be supplied from an ungrounded isolated power system equipped with a line isolation monitor* (LIM). The LIM should: <ol style="list-style-type: none"> (1) provide a continuous reading of the total hazard current; (2) indicate a normal situation (green light) when the system is isolated from ground; and (3) indicate a fault situation (red light and audible alarm) when the leakage current exceeds the allowable threshold value (typically 5 mA). <p><i>* Line insulation monitoring achieves a similar degree of protection and monitors the insulation resistance of all conductors. Preset response values are typically 5 kΩ for a 24 V_{dc} supply and 2.5 kΩ for a 12 V_{dc} supply.</i></p>	Note Note Note Note
23. Grounding of wiring	2	All wiring both inside and outside the chamber that is monitored by a LIM should be grounded and bonded in accordance with NFPA 70 Article 501-16 or relevant national regulations covering this practice. This applies to the practice of using bonding jumpers to ensure adequate bonding.	Note
24. Equipment outside of chamber	1	(1) All equipment that must remain functional for the safe completion of the treatment after activation of the deluge system should be adequately waterproofed.	N/A
	2	(2) Where used, conduits should be waterproof and, as applicable, be equipped with drains.	N/A
	1	(3) All electrical circuits should be protected so that flooding by water does not constitute a further hazard.	N/A
	1	(4) All electrical equipment should meet national regulations.	Note
25. Ground Fault Interrupter (GFI)	2	(1) All external chamber electrical power users, including patient support equipment, should be supplied from a GFI, a line-isolating transformer system - providing an inductive link only, as well as indicating/warning lights. "Earth-leakage" protection is a practice used in some countries and may fulfill the above requirements.	Yes
	1	(2) A secondary circuit sensing system should be used to sense single or balanced capacitive-resistive faults, as well as current leakage to ground.	Yes
	1	(3) The sensor should be set to activate at a fault current of 75* mA within 15 ms. <i>*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.</i>	Yes
	1	(4) The full load rating of the GFI should be twice the current rating of the equipment being used.	Yes

APPENDIX D

REFERENCES AND ADDITIONAL READING

REFERENCES

- (a) American Society of Mechanical Engineers. Safety Standard for Pressure Vessels for Human Occupancy, ANSI/ASME PVHO-1-1997, New York, USA, 1990. (www.asme.org)
- (b) American Society of Mechanical Engineers (ASME) PVHO-2, Safety Standard for Pressure Vessels for Human Occupancy: In-service Guidelines for PVHO Acrylic Windows, 2003
- (c) National Fire Protection Association. Standard for Health Care Facilities, NFPA 99, Quincy, USA, 1999. (www.nfpa.org)
- (d) European Standard EN 19431:2006, Pressure Vessels for Human Occupancy (PVHO) – Multiplace pressure chamber systems for hyperbaric therapy, 2006.
- (e) Undersea and Hyperbaric Medical Society. Guidelines for Clinical Multiplace Hyperbaric Facilities, Kensington, USA, 1999. (www.uhms.org)
- (f) National Fire Protection Association. National Electrical Code[®], NFPA 70, Quincy, USA, 1999. (www.nfpa.org)
- (g) Compressed Gas Association. Handbook of Compressed Gases, Arlington, USA, 1989.
- (h) Compressed Gas Association. Cleaning Equipment for Oxygen Service, G-41, Arlington, USA, 1985.
- (i) American Society for Testing and Materials. Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen Enriched Environments, G-93, West Conshohocken, USA, 1996.
- (j) Standards Australia. Work in Compressed Air and Hyperbaric Facilities, Part 2 Hyperbaric Oxygen Facilities, AS 4774.2, Sydney, Australia, 2002.
- (k) American Bureau of Shipping. Rules for Building and Classing Underwater Vehicles, Systems and Hyperbaric Facilities, American Bureau of Shipping, New York, U.S.A. 1979. (www.eagle.org)
- (l) Bureau Veritas. Rules and Regulations for Classification of Submersibles, Bureau Veritas DSM Marine Technical Publications, Paris, France, 1989. (www.bureauveritas.com)
- (m) Det Norske Veritas. Rules for Certification of Diving Systems, Det Norske Veritas, Hovik, Norway, 1988. (www.dnv.com)
- (n) Germanischer Lloyd. Rules for Classification and Construction, Offshore Technology, Germanischer Lloyd, Hamburg, Germany, 1991. (www.germanlloyd.de)
- (o) Lloyd's Register of Shipping. Rules and Regulations for the Construction and Classification of Submersibles and Diving Systems, Lloyd's Register of Shipping, London, U.K. 1989. (www.lr.org)
- (p) International Standard. Oxygen concentrator supply systems for use with medical gas pipeline systems. ISO 10083:2006(E). Geneva, Switzerland. 2006 (www.iso.org)
- (q) Naval Sea Systems Command, U.S. Navy Diving Manual, Revision 6, Washington, D.C. U.S.A. 2008.

ADDITIONAL READING

- (a) Workman WT. Hyperbaric Facility Safety - A Practical Guide. Best Publishing Company, Flagstaff, Arizona, USA, 1999.
- (b) National Fire Protection Association. Fire Hazards in Oxygen-Enriched Atmospheres, NFPA 53, Quincy, USA, 1994.
- (c) National Fire Protection Association. Recommended Practice on Materials, Equipment and Systems Used in Oxygen-Enriched Atmospheres, NFPA 53, Quincy, USA, 1999.
- (d) Schram, Peter J. and Earley, Mark W. "Electrical Installations in Hazardous Locations." National Fire Protection Association, Quincy, USA, 1994.
- (e) Nuckols ML, Tucker WC, Sarich A.J. Life Support Systems Design: Diving and Hyperbaric Applications. Pearson Custom Publishing, Boston, USA, 1996

APPENDIX E

NON-COMPLIANCES, RECOMMENDATIONS AND COMMENTS

A-NON-COMPLIANCES:

1. **Chamber grounding:** The resistance between the chamber and ground should never exceed 1 Ohm. No provision appears to have been made for grounding the chamber.

Recommendation: Fit a suitable grounding conductor between the chamber and building ground (preferably earth ground and independent of the building electrical system).

2. **Depth gauge (Caisson gauge) in treatment lock:** The treatment lock should be fitted with a Caisson gauge to allow the tender to (1) determine whether treatment is going according to plan, (2) ensure that there are no leaks into the chamber that the operator is not aware of, and (3) surface the chamber safely in the event of an emergency situation.

Recommendation: The Caisson gauge appears to have been left out of the refit and should be replaced into the treatment lock.

3. **Fire alarm:** No arrangement is in place for the signaling of any emergency that may occur within the unit. This includes fire or medical emergencies, loss of gas supplies during a treatment and so on.

Recommendation: An alarm and/or emergency signaling device should be provided at the operator's console for signaling either a telephone operator, who is responsible for the hospital or the fire or emergency medical departments directly. A direct alarm/monitoring system coupled to fire department is preferable (where this is either feasible and of practical value).



4. **Fire detection & extinguishing in the chamber & compressor locations:** No provision has yet been made for fire or smoke detectors in the unit. No fire extinguishers have been placed in the chamber or the compressor locations.

Recommendation: Smoke alarms should be fitted in the chamber and the compressor rooms. Suitable warning signs should also be in place to alert personnel and visitors to the obvious fire hazards of a hyperbaric facility, where fire extinguishers are located, and so on. The chamber and compressor rooms should have suitable, at least hand-held fire extinguishers installed.



5. **Fire extinguisher in the chamber:** The chamber has not been fitted with a suitable hyperbaric fire extinguisher. This is a mandatory, minimum requirement for any and all multi-place hyperbaric facilities, including diver and medical patient treatment units.

Recommendation: Fit a hyperbaric fire extinguisher in the treatment lock and ensure that staff are fully trained to use this. See also the subsequent comment under B-10 for regular maintenance requirements.



6. **Insufficient air supply system redundancy:** The facility makes use of a single LP air supply system using a suitable, 95 cfm compressor. However, in the event of a compressor failure, or a power outage, this unit will not be able to continue with a diver treatment; a matter regarded as a medical emergency in itself.

Recommendation: There are two ways of addressing the problem at this hospital, viz. coupling into the hospital air supply system, or installing a bank of HP air-cylinders.

In addition, it should be determined whether the hospital electrical generator is capable of running the existing Quincy compressor.

The industry standard is a supply of air cylinders with sufficient capacity to start and complete a TT6 with extensions, or, where the facility advertises the ability to offer treatments to Cx 30 or USN TT6-A tables, then sufficient supplies to cope with these. Using 200 bar, 50 litre capacity high pressure cylinders, then the following supplies would be needed:

TT5	4 cylinders charged to 200 bar
TT6	7 cylinders charged to 200 bar
TT6 + max. extensions	12 cylinders charged to 200 bar
TT6A	14 cylinders charged to 200 bar

TT6A + max. extensions	18 cylinders charged to 200 bar
Cx 30 (modified)	15 cylinders charged to 200 bar

7. **Oxygen analyzer:** There is currently no oxygen analyser installed in the chamber. This is a mandatory requirement as it is imperative that the oxygen content of the chamber be monitored constantly and never allowed to exceed 23.5%. The remains a significant fire hazard and the chamber should not be used without this essential piece of safety equipment.

Recommendation: Purchase a suitable, reasonably priced oxygen analyser with at least a high-level audible and visible alarm feature. The analyser should be able to detect oxygen in two ranges, viz. 0 – 25% and 0 – 100%. The analyser circuit will require a flow meter as well as a flow metering valve. Refer also to the comments under C-4 below.

DAN is available to assist in the selection of a suitable model if necessary.

8. **Oxygen isolating valve in the chamber room:** Oxygen supplies are usually stored outside the chamber room to ensure a degree of safety in the event of fire in either the chamber room, or the gas supply room/location. It is necessary to fit an isolating valve into the line where the oxygen supply enters the chamber room, to enable the operator to isolate oxygen supply in the event of a fire.

Recommendation: There are two options here.

(1) The oxygen cylinders can be moved from the existing gas supply location to the back wall in the treatment room. This will enable much better monitoring and control.

(2) A suitable, quick acting shut-off valve should be installed between the roof connect and the chamber – note that ball valves may not be used on oxygen supply lines with a pressure in excess of 125 psi (8.6 bar).

9. **Safety valve:** The chamber has not been fitted with a suitable safety valve. This is a mandatory requirement for any pressure vessel and the chamber should not be used without such a safety device.

Recommendation: Install a suitably sized safety valve directly onto the chamber shell, including internal and external isolation valves that remain wired open at all times. Suitably-size implies that the valve will be able to cope with the maximum inflow of air (currently 95 cfm) while reducing the pressure at the same time.

The set pressure should be set at a level no more than 10% above the maximum intended treatment depth, which in case of air diving would be 182 FSW (79 psi) but more appropriately for this hospital-based chamber, no more than 110 FSW (48 psi).

Based on the final decision as to what tables will be offered, the set pressure could be as low as the maximum safe depth to avoid oxygen toxicity, which would be 3 ATA, implying a set pressure of 72 FSW (31 psi).

Should a higher rated safety valve be selected, then it would be wise to consider the inclusion of an additional safety valve to prevent inadvertent pressurisation to below safe oxygen treatment depths.

A simple T- piece, external isolation (ball) valve and safety valve set to 72 FSW (31 psi) can be installed in any line that has direct access to the treatment lock chamber pressure. A low flow, inexpensive safety valve can be selected. The prime purpose of this device would be to provide the operator early warning that a safe oxygen treatment depth has been exceeded, prior to the consequential effects of oxygen toxicity being realised. Where an air dive to treatments at depths in excess of this level are planned (Comex 30, TT6A, etc), the ball valve is used to isolate this safety device.

10. **Viewports:** The chamber viewport windows are dated 1985 and have thus exceeded both their initial design life, as well as the potential life-extension period as allowed for by ASME PVHO-2.

Recommendation: According to the codes and to accepted safety practices, the viewports should be replaced. However, inspection of the windows clearly shows that the condition is still excellent. It is therefore the qualified opinion of the author that, based on limiting treatment depths to less than 3 ATA (the windows are designed for use at 10 ATA), and based on at least 2 yearly, mandatory visual inspection according to the ASME PVHO-2 requirements, this replacement requirement could be regarded as a future replacement priority and the chamber be allowed to operate using the existing windows.

Administration and Operational Considerations:

11. **Documentation:** The following documents and documented systems are not yet in place:

- (a) Integrated operational and safety policy
- (b) Written appointments* and/or official delegation of duties and responsibilities
- (c) Pre- and post treatment operator/tender checklists
- (d) Clear rules and regulations for the use of the chamber, including emergency equipment
- (e) Documented emergency procedures
- (f) Patient indemnity form

The IDAN Risk Assessment Guide provides clear reasoning behind why it is important to ensure that each facility has an integrated, documented and implemented management and operating system. This system of documentation is vital to ensure that all staff understand their duties and responsibilities, that management has adequately covered itself in terms of its own responsibilities and liabilities, and that the operating system as a whole is correctly implemented, monitored and maintained.

* All safety critical staff (facility manager, safety director or officer, technical officer) should be appointed in writing, with their responsibilities and liabilities clearly detailed. Appointments should be made based on the individual's competence, by virtue of their training, knowledge and experience, as well as their understanding and acceptance of their responsibilities. This would further ensure that all safety aspects are understood and fulfilled, provide traceable delegation and acceptance of responsibilities, and provide a degree of indemnity to management in the event of any mishap.

Recommendation: The medical director should commission the compilation of a documented policy, procedure and instruction manual, and ensure full implementation thereof. An integrated policy, ensuring compliance with any national, regional and municipal regulations, together with all the associated equipment, should be established and enforced by suitably competent and experienced personnel.

DAN is able to provide a guidance document to assist with the compilation of a manual.

12. **Safety Drills and Management Audits:** The only effective way to assess the effectiveness of safety procedures and management controls is through regular practices (drills) and system reviews (audits). Failure to assess these safety fundamental issues could well result in serious damage and injury during any emergency situation.

Recommendation: All staff should be thoroughly trained and experienced in the use of emergency equipment and the following of emergency procedures.

The medical director should ensure that all drills are practiced both during initial training, as well as during refresher sessions. Sporadic, unannounced drills have a significant impact on the ability of staff to react automatically and instinctively during emergency situations.

Periodic reviews (audits) of the operating and safety management systems will assist in determining the effective functioning of these systems, and enable needs for additional training, revision of procedures and equipment replacement to be determined. These reviews should include logs and documentation systems, and should ensure that logs have been signed by the appropriate responsible persons.

13. **Other considerations:** Safe and comprehensive protocols that 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 should be compiled, documented and provided as part of the training of all staff.

Non-obvious but combustible materials such as newsprint must be kept out of the chamber. Many newspapers are printed using volatile inks.

The medical director should establish minimum staff qualifications, experience and complement based on the nature and size of the chamber facility, as well as the type of treatments normally provided. These requirements should be documented and made available during facility surveys.

Trainees and personnel without the requisite hours of practical experience should only operate within the facility under the direct supervision of the appropriate technician, doctor or qualified staff member.

14. **Maintenance system:** A formal and recorded maintenance system is not yet in place. Premature system failure can jeopardize the safety of patients, tenders and operators.

Recommendation: Compile, document and implement an adequate and effective maintenance program requires that addresses at least the following elements:

- (a) Formal appointment of competent personnel, with delegated authority to maintain the systems.
- (b) Regular maintenance inspections, change-outs, calibration and testing, including pressure testing, hydro-testing*, leak testing of all piping systems and safety valve resetting.
- (c) Preventative maintenance for compressors and other operating machinery.
- (d) Ensuring that only qualified staff should be permitted to operate or work on any gas handling equipment.
- (e) The facility should maintain a documented set of equipment oxygen cleaning instructions, including post-cleaning inspection requirements.
- (f) All controls and pipes should be clearly labeled to assist fault-finding, servicing training.

* Hydro testing is not feasible for the chamber in the location installed, as the added mass of the water may indeed exceed the floor bearing capacity. However, pneumatic testing for regular pressure vessel testing is a suitable substitute, depending on national regulations. Hydro-testing is only mandated where repairs to the chamber are done which involve any welding to the pressure retaining parts of the vessel.

B-RECOMMENDED ITEMS:

1. **Air analysis:** Regular air quality analysis and recording of supplies to the chamber is always strongly recommended. This will provide valuable information on the condition of the compressors and filtration equipment.



Regular analysis of at least CO₂, CO and oil content levels should be conducted.

The Quincy compressor used for the chamber is not an oil-free compressor, there is no post-compression refrigerant dryer installed and hence the quality of the air will be, at best, suitable for breathing* purposes only. This implies that the air is not likely to be fit for oxygen-enriched environmental use, or for any medical-air application. Regular testing will be imperative to ensure that the oil content is maintained within accepted limits.

* Breathing air (ref. Appendix A, pg 30) is defined as air suitable for diving, SCUBA, SCBA and occupational applications, specifically with an oil-content of less than 5 mg/m³. This is usually termed as CGA Grade D or E air. Medical air (CGA grade N), which is oxygen compatible, has an oil-content of less than 0.1 mg/m³. This level of purity can be achieved where a suitably-rated refrigeration dryer is installed after the compressor, and the air filtration units are selected to produce oil-free air. (The hospital uses an oil-free compressor as well as a refrigeration dryer, which thus ensures oil-free, dry and medical-grade air.)

2. **Alternative breathing gas:** In the event of a fire inside the chamber, or should the chamber internal environment become unbreathable for any reason, the facility should have a mechanism for providing clean air to the occupants. This is typically achieved using quick-acting ball valves placed immediately prior to the gas entering the chamber (i.e. after the pressure reducing regulator).

However, where the oxygen BIB system is used to provide an alternate gas to occupants inside the chamber, there are added complications to be considered. BIBS lines and masks must, at all times, be kept oxygen clean and should only be supplied with oil-free gases such as oxygen or Medical Air (ref. Appendix A, pg 30).

The options are thus to use either (1) an oil-free compressor, or (2) Medical Air supplied in HP cylinders from a vendor, or (3) the suitable filtration of compressed air (oil content < 0.1 mg/m³). In the case where none of the above options can be employed, the oil content of the air must be tested immediately after using the system, and where this level is above 0.1 mg/m³, the entire chamber oxygen supply and BIBS delivery system, up to and including the mask demand regulator, will require oxygen cleaning.

3. **Alternative breathing gas to chamber operator:** In the event that the environment surrounding the chamber becomes compromised (toxic fumes or smoke), the operator is required to remain at the control console until all the chamber occupants have been safely evacuated.



Recommendation: An external breathing apparatus (e.g. SCBA, demand breathing mask) or smoke hood should be provided for use by the operator.

4. **Anti-suction devices:** The pressure gauge internal sensing ports are not fitted with anti-suction devices. These basic devices ensure that the sample or gauge line cannot be inadvertently blocked by occupants or loose materials, thus providing a false depth, reference pressure or analysis reading.

Recommendation: Fit basic anti-suction devices to all internal venting points. These devices may be either a sintered filter, or preferably, a short length of pipe, which has been drilled with several holes and is fitted into the venting point. The pipe remains open-ended.



5. **Back-up or emergency communication system:** No system is in place in the event that the communication system fails.

Recommendation: A sound-powered telephone or emergency communication system should be fitted. The original sound-powered phones that were installed are still available and may be suitable for re-installation (the new cables being fitted have sufficient conductors to be utilized for this).



6. **Contamination of air intakes:** Suitable signs should be placed in the compressor room to warn against the storage of any fluids with toxic vapours that could be entrained into the compressor intake. Paints, solvents and cleaning materials must not be stored anywhere close-by to the compressor.



7. **Emergency lighting inside the chamber:** In the event of a power failure, and the possibility of additional complications (confusion, panic by patient, operator not paying attention, etc), emergency lighting in the chamber is required.

Recommendation: Install a suitable diving torch (flashlight) in the treatment lock and ensure that the batteries are checked frequently.

8. **Escape system:** All recompression chambers should be fitted with an escape system to allow occupants to surface the chamber in the event of the operator being unable to do so (fire, physical injury, accidental damage to piping systems, blockages, etc.)

The escape facility is usually as basic as a shell penetration fitted with valves externally (and always wired open) and internally (kept closed and fitted with an anti-suction device). A minimum line size of 1" is recommended. Both locks require this facility.

9. **Exhaust gas outlets:** Chamber exhaust gases may contain elevated levels of oxygen, rendering the area around the exhaust point a fire hazard.

Recommendation: Chamber exhausts have been piped to a point outside the chamber building that is away from obvious congregation points. Sign-boards should be used to indicate that this point remains a fire hazard (especially to keep smokers away).



10. **Fire extinguishers:** Where used within confined spaces, such as inside a recompression chamber, fire extinguishers should not be relied upon to work under emergency situations without regular checking of content and especially function. This requires actual testing of the hyperbaric extinguishers, which in turn requires that the facility is able to refill and recharge these extinguishers. Checking pressure levels only is not sufficient.

Six monthly inspections of extinguishing media and full system functioning should thus be conducted.

This item should be added to the facility maintenance instructions, viz. the portable fire extinguisher must be checked by a competent person at least every six months.



11. **Glycerine-filled pressure gauges:** While a relatively scarcely reported source of oxygen fires, it should be pointed out that Bordon-tube gauges may indeed develop fatigue cracks over a period of time, allowing the glycerine, usually used to damp the gauge needle from vibrations, to seep into the piping system. Glycerine is a known fuel source.



Recommendation: Only use dry, oxygen-clean and oil-free identified gauges for all chamber gas indicators, especially oxygen pressure indicators.

12. **Hearing protection:** Sound levels in excess of 85 dBA are known to cause great discomfort to occupants, increasing anxiety and distress. Appropriate pressurization silencers will keep sound levels to below these levels.

Recommendation: Personal protection equipment should be made available to all occupants. Note that conventional industrial equipment may well be suitable but must be examined for the ability to equalize pressure.



13. **Labeling:** All chamber valves, controls and associated pipe-work should be clearly marked to assist in fault-finding and to ensure that new staff do not become confused during emergency situations.

14. **Oxygen pressure monitoring:** There is currently no means of determining oxygen pressure as supplied to the chamber breathing system from the operator's console. It is important that any drop in supply pressure be noted by the operator so that appropriate contingency plans can be enacted.

Recommendation: Together with the installation of a shut-off valve (ref. A-8 above), a suitable pressure gauge should be installed at the point where the oxygen is supplied to the chamber.

15. **Particle filters:** The HP oxygen (and air supply systems) should be fitted with suitable (at least 10 micron) in-line particle filters before the regulators. Dirt is a known cause of regulator failure (creeping upwards of downstream pressure) as well as a fuel source for oxygen fires.



16. **Piping materials:** While recompression chambers and their piping penetrations are generally constructed in steel, the piping (supply) systems, and especially the oxygen piping system should comprise materials

that do not corrode or allow the contamination of the breathing gas. The San Andres chamber appears to have galvanized steel piping for the air supply system. This is not considered a safe and advisable practice.

Recommendation: This is not considered an immediate hazard, but if the chamber is to be refurbished in the future, then this pipe should be replaced with a suitable material such as copper, or even stainless steel (which-ever is less expensive).

17. **Quality control of oxygen:** A formal procedure should be in place for staff to check the content of all oxygen supplied to the facility. Where analysis certificates are not provided with oxygen cylinders, the facility should sample the oxygen each time that a new cylinder is coupled to the supply manifold. This reading should be recorded in the chamber log-book.

General recommendations for improved safety: The follow items of a more general nature are offered for consideration either during a suitable upgrade program, during maintenance change-outs, or as part of good house-keeping.

18. **Gauges:** Only use oxygen-clean and oil-free identified gauges for all chamber gas indicators, especially oxygen pressure indicators.
19. **Gauge isolation valves:** All depth gauges, and gauges used to indicate the pressure of critical supplies should be fitted with isolating valves in case of gauge failure (failure of bourdon tube could compromise the integrity of a pressure circuit).

Air circuits and oxygen circuits with maximum operating pressures below 8.6 bar may use quarter-turn (ball) isolating valves, wired in the open position using frangible wire. However, oxygen circuits with pressures above 8.6 bar should use rising stem (needle) isolating valves.

20. **Sealant tape:** PTFE (Teflon™) sealant tape is a common product used for ensuring gas-tight seals. However, standard PTFE tape is not oxygen compatible as it is produced using an oil-lubrication process. PTFE tape is also a known source of phosgene gas when exposed to high temperatures. Oxygen-compatible PTFE tape is generally available and should be used, preferably throughout the facility (to avoid confusion), or at least on all oxygen joints.



21. **Lubricants:** High pressure lubricants, such as Christo-lube™ or Halocarbon™, are excellent but costly oxygen compatible products. The use of these products may be restricted to high pressure and oxygen applications only. A suitable, oxygen compatible, low-pressure application, silicone-based lubricant (e.g. Rhodosil Pate - a Rhone-Poulenc product, or Dow Corning products) is an economical solution for general purpose lubrication of seals not exposed to pure oxygen.



22. **CGA Handbook:** It is recommended that the facility acquire a copy of the CGA Handbook (reference 5 in Appendix D above). This publication provides good guidance for the handling and storage of high pressure and/or dangerous gases.

Electrical circuits:

The electric systems and standard of workmanship at the facility are generally in-line with diving system practices. The following recommendations and comments are thus offered for future improvements and safety considerations.

23. **Chamber power supplies:** When supplying any electrical power to the chamber internal circuits, only utilise double-insulated, *isolation* transformers to prevent any sparking, or overload or fault conditions from causing an increase in current to any chamber appliance.
24. **Chamber connectors:** Proper hyperbaric-approved pressure-proof connectors should be used for all chamber penetrations. Glanded direct-through wiring is not an approved hyperbaric solution and failure can occur where wiring creeps back through the gland while under pressure.
25. **Power reserves:** The requirement for reserve power applies to lighting (inside and outside the chamber), communications, analysers, air-supply systems, alarm systems and any medical devices.

Emergency lighting around the chamber should be in place, and where communicators and/or analysers are not fitted with internal battery back-up systems, these should be connected to a basic computer UPS supply system.

26. **Isolation monitoring:** A Line Isolation Monitor (LIM) is recommended for monitoring the isolated power supply and detecting any line-to-ground faults in any of the chamber internal equipment[†] wiring circuits. The LIM should:

- (a) provide a continuous reading of the total hazard current;
- (b) indicate a normal situation (green light) when the system is isolated from ground; and
- (c) indicate a fault situation (red light and audible alarm) when the leakage current exceeds the allowable threshold value (typically 5 mA*).



[†] Currently, the only planned internal electrical equipment will be the chamber speakers, and perhaps the Sound-powered Phones. These are not considered hazardous and the installation of a LIM is intended where equipment such as electrical motors, internal lighting or medical equipment are to be installed.

* Line insulation monitoring achieves a similar degree of protection and monitors the insulation resistance of all conductors. Preset response values are typically 5 kΩ for a 24 V_{dc} supply and 2.5 kΩ for a 12 V_{dc} supply.

Maintenance:

27. **Bilge cleaning:** The area under deck-plates is a known location for the collection of dust, lint, fluff, fluids and numerous other surprises. Dust, lint and fluff are a ready source of fuel and present a fire hazard. Condensation and other fluids collect in the bilge areas and are the most common cause of corrosion in chambers. Biological waste will breed bacteria and promote infection.

Recommendation: Bilge areas should be cleaned and disinfected at least every week. When the chamber is not in use, the bilges should be cleaned after the last treatment and then at least before treatments recommence.

There is a small amount of corrosion already in evidence, further illustrating the need for inspection. This corrosion must be attended to as soon as practically possible before it leads to significant thinning of the chamber shell.

28. **Flexible hoses:** Flexible hoses used for low pressure (under 10 bar) are not a physical safety hazard in terms of failure; however, as hoses deteriorate over time when exposed to the elements, their unexpected failure will cause a treatment to be aborted.

Recommendation: It is strongly recommended that the flexible hoses used by this facility be visually inspected regularly for signs of deterioration or damage, that they be protected from obvious mechanical damage, and that they are at least annually pressure tested (possibly during the reported annual compressor service and inspection). All inspections should be recorded.

29. **Gauge calibration:** Depth gauges should be calibrated at least once a year to ensure appropriate confidence in medical treatment efficacy. It would be deemed acceptable for the unit to run a calibration exercise at least annually where one gauge is selected to record settings and the remaining depth and Caisson gauge are compared to this gauge over the full range of treatment depths. Acceptable accuracy is deemed as the level where deviation would cause a change to the treatment protocol, or where the safety of the recompression chamber vessel could be affected. All tests should be documented.

30. **Oxygen analyser:** The analyser (once fitted) should be calibrated (spanned) prior to each and every treatment. Refer to the additional guidance provided in section C-4 below.

31. **Oxygen cleaning:** The facility should maintain a documented set of equipment oxygen cleaning instructions, including post-cleaning inspection requirements. Where all cleaning is done by external consultants, the facility manager should insist on a cleanliness certificate and maintain a record of all oxygen cleaning done on the facility equipment.

32. **Particle filters:** All HP in-line filters (once installed) should be cleaned at least annually, especially where gas is supplied from external vendors.

33. **Safety valves:** Safety valves should be checked periodically to ensure that the set pressures have not changed and that reseal pressures can be achieved (safety valves that operate infrequently, especially in areas of high temperatures and low utilisation, may not reseal satisfactorily after venting, which can result in the inability to maintain the chamber at the required treatment pressure).

These valves should be function tested annually, and the ability of the valve to crack at a pressure approximately 5% before set pressure (i.e. the valve should start to hiss at this level), open fully at set pressure, and then to reseal at a pressure of at most 7% below set pressure should be verified. (It may be

worth considering the inclusion of the venting of a safety valve during training, so that the incumbent chamber operators are aware of the typical noise levels and thus do not over-react in the unlikely event of a real emergency.)

34. **Workshop facility:** A suitable, dedicated maintenance area which is equipped with dedicated tools, lubricants, sealants and instruments, is required to enable personnel to affect repairs, replacement and cleaning with minimum “downtime”.

C-COMMENTS:

1. **Closed circuit television (CCTV) monitoring:** The lay-out of this system is such that the chamber operator cannot maintain visual contact with the occupants while remaining at the control station.

Recommendation: Modern CCTV systems are available at low cost and with multiple views on a single LCD screen. Internal chamber cameras are also available on the market.

This system may also be used to record difficult treatments and for training purposes.

2. **Discrete (private) communications:** It is advisable to consider the ability of the chamber tender and the operator to be able to communicate discretely in some instances, specifically where the patient is in distress and does not need additional concerns.



Recommendation: A headset and boom microphone option is usually available on most communications devices and should be considered. Alternatively, where a sound-powered phone is considered for emergency communications (ref. par. B-5), this may serve as a means of communicating with discretion.

3. **Documented corrective maintenance system:** This is considered as an advantage, especially where a facility is not operated on a regular (daily) basis. 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.
4. **Regular & effective calibration of the oxygen analyser** is required in order to ensure (1) that the chamber environment can be accurately controlled to below 23.5% oxygen, and (2) that the content of the HP oxygen cylinders can be safely assured.

There are several considerations that affect the reliance on the analyser to provide safe and effective readings.

- (a) In general, spanning of analysers using ambient conditions (assumed to be 20.7 to 21% oxygen) is effective enough, as it is the percentage difference between ambient and 23.5% that provides the safety margin.
- (b) Accuracy of readings is directly proportional to the flow-meter setting; specifically, the flow rate at which calibration was performed.
- (c) Greater flow rates ensure more rapid detection of changes in oxygen content. However, greater flow-rates also increase the fuel cell voltage output (which has the effect of increasing the reading, irrespective of actual oxygen content).
- (d) Flow rates are directly proportional to inlet pressure. The deeper the treatment, the higher the flow for a given valve setting. Similarly, during ascent, the flow rate will effectively reduce.
- (e) Spanning of analysers must be done within $\pm 5\%$ of the expected reading. This has the effect that spanning at ambient oxygen levels does not calibrate the instrument for a reading of 99% oxygen.
- (f) As fuel-cells approach the end of their useful life, the calibration setting increases, as the output voltage of the cell at oxygen levels drops dramatically.

The simple solution to these considerations would be to operate as follows:

- (a) Record and maintain exact flow rate levels for readings after calibration. (If the instrument has been spanned at 4 l/min, then all subsequent measurements must be effected at this flow rate.)
 - (b) Calibrate the instrument using a known supply: A calibration gas is the correct way; either using a vendor certified HP cylinder, or a specially procured and dedicated calibration gas cylinder.
 - (c) Always span the analyser before each and every dive.
 - (d) During periods of known inactivity, remove the fuel cell, package it in a sealed plastic bag with excess air squeezed out, and store in a refrigerator. This will extend fuel cell life.
5. **Surfacing rates:** During medical and/or situational emergencies (fire in the building), it is important to be able to surface the chamber at least within 6 minutes from 65 FSW. It does not appear that this is possible with the current exhaust system and this characteristic should be tested once the chamber is operational, and if insufficient, an alternative rapid-exhaust valve should be considered.