

ECHM Recommendations for Safety in multiplace medical hyperbaric chambers

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E C H M RECOMMENDATIONS FOR SAFETY IN MULTIPLACE MEDICAL HYPERBARIC CHAMBERS

1-PRINCIPLES

1.1-Scope of work

The purpose of this document is NOT to produce a new set of rules, standard or regulations for the safety of H B O. These rules, standards and regulations exist and are available in various forms and countries. A list of the major international ones is given below for reference.

This document is intended to be guidelines for the manager or any responsible person in an H B O operation to help him making sure that all necessary safety precautions are taken care of properly.

1.2 Risk assessment

To make sure safety precautions are adapted to the situation, a risk assessment is necessary. This is depending on the type of hyperbaric installation, the patients and the indications, as well as the number of exposures carried out on a regular basis in the hyperbaric facility.

This document will not provide answers to all questions, it is only guidelines. An adapted response to eliminate the risks and to reduce the unavoidable ones to an acceptable level must be established under the manager control for each particular Hyperbaric Centre.

1.3 List of reference documents

European Directives :

CEN Medical devices:	93/42/CE	dated 14 June 1993
CEN Pressure vessels:	97/23/CE	dated 29 May 1997
CEN Noise at work :	86/188/CE	dated 12 May 1986
CEN Chemical agents:	98/24/CE	dated 07 April 1998
CEN Electric devices / explosive atmospheres	94/9/CE	dated 23 March 1994
CEN Electric devices / electrocution	73/23/CE	dated 19 February 1993

Standards : Air quality standard (medical air, breathable air...)
ASME PVHO 1998
NFPA 1998
UHMS (Monoplace 1991 and Multiplace 1994 - HBO Chamber Safety)
ECHM (Training standard) 1997

Other documents : Many independent control organisms have produced rules or certification policies for hyperbaric and diving systems which may be used for conformity assessment of pressure vessels for human occupancy of HBO chambers (Bureau Véritas, Germanische Lloyd, Lloyds, DNV,...)

1.4 Major points to be considered

Establishing and controlling a safety policy, at work for the attendants as well as in medical practice for the patients, is one of the duties of the manager of the Hyperbaric Facility. Sub-delegation of responsibilities should be clearly set and made known to the personnel.

The equipment used for HBO treatment is susceptible to generate risks both to the personnel and to the patients, therefore some construction and maintenance standards should be referred to for the equipment control and for the monitoring of the maintenance and in case of any modification carried out on that equipment. This topic includes fire protection and fire extinguishing systems.

Operational procedures need to be specified, posted and logged.

2 - MANAGEMENT AND ORGANIZATION

2.1 Responsible persons

It is the duty of manager of the Hyperbaric Centre to organize safety in the facility and he should designate in writing who is in charge of:

- Equipment, its maintenance and control (from compressed gases supplies to the chambers, the controls panel, and the exhaust of gases and fire fighting equipment outside and inside the chambers),
- Running the sessions and monitoring the operation,
- Informing the patients, controlling their personal items and objects eventually carried inside the chamber.

2.2 - Supporting documentation

*** Safety manual**

The safety manual is prepared and signed by the manager of the facility; it should include all information necessary to carry out the hyperbaric sessions safely, including the description of duties of the personnel involved. The content of this Safety Manual should be known by all and specific information should be given to new comers to make sure they are perfectly aware of its content.

*** Hyperbaric Equipment Construction Data Book (As built)**

A technical document should contain all information concerning the plant, as built drawings, all certificates with a list and dates of validity for easy check, basic operational procedures, maintenance program recommended by the manufacturer, and logging of all modifications carried out on the equipment.

*** Maintenance register**

Based on the manufacturer recommendations, a register of maintenance should be opened to log all actions of the maintenance team, in particular formal inspections, re-certifications, and spare parts changes. Near missed or break down should also be entered for further actions.

*** Compression and decompression procedure manual**

All pressure profiles used in the treatment should be categorized and identified with proper description. This includes decompression procedures applicable to the exposed personnel on the occasion of the attendance of the patients.

Any emergency compression (access), decompression (evacuation) or recompression (in case of DCI symptoms) procedures to be used for the attendants should also be in that document.

*** Day to day logging of personnel pressure exposures**

A register of exposure should receive information about individual staff exposures, and the same data should be logged in a personal log-book supplied by the employer to each person qualified to be exposed to pressure.

2.3 - Personnel training / medical fitness

Any person exposed to pressure should be fit to do so. This is based on occupation medical fitness to undergo pressurization. A specific assessment is needed on a yearly basis. A certificate of fitness should be issued, and eventually entered in the personal log-books.

The content of medical examination may be under national rules. If not, it should be defined and agreed with the concerned occupational doctor.

2.4 - Relationship with external emergency services

A joint visit of the plant with the Fire Brigade in charge of the place is highly recommended and the conclusion should be a jointly defined contingency plan for fire outside the chamber and help in case of fire inside.

2.5 - Safety posters on site

Through out the plant, where specific safety information is needed, proper posters should remember to the patients and to the personnel the applicable safety rules (Non smoking area, items not to be taken in the chamber, maximum value for oxygen monitoring and action in case of high alarm signal...)

At the lock attendant position, information on panel operation should be clearly displayed (valve function, positions, piping diagrams, emergency items...)

3 - EQUIPMENT

3.1 - Construction of Hyperbaric Chamber

*** Pressure vessel**

Specific construction and inspection rules apply to pressure vessels according to various national rules. After 2002, European pressure vessels regulation will have been harmonized under the Directive : CEN Pressure vessels, 97/23CE, dated 29 May 1997.

*** Architecture**

Basically the number of chambers in an installation should be such that, in case of emergency it should be possible to enter the treatment chamber and provide assistance inside. The minimum is a 2-compartment installation, one chamber being kept at atmospheric pressure to give access. It is generally considered acceptable to carry out decompression of personnel in that access chamber provided a procedure is prepared to free that chamber quickly to face the need to enter the main chamber.

Patient access to the treatment chamber is of primary importance for the personnel and all effort should be made to provide mechanical help for handling beds and stretchers when the entrance doors are not with easy and wide access. Many chambers derived from diving chambers engineering are very poorly designed in this respect. In addition this is a serious hazard in case of emergency evacuation.

* **Electric devices**

Electricity may cause two types of hazards : Electrocution and Fire.

Electrocution prevention

Any electrical medical device in contact with the patients should be protected against the hazards of electrocution for the patients in accordance with medical rules applicable to such medical devices.

Any electrical device used in the chamber as tools or equipment should be protected against electrocution as a tool or equipment used in a conductive environment (CEN Electric devices, electrocution, 73/23/CE, dated 19 February 1993).

Fire precautions

Fire may be triggered in the chamber either by conductors overheating (short circuit) or by sparks. Due to the high partial pressure of oxygen always present in compressed air, fire will develop extremely fast if material burning in compressed air is present at the place of fire trigger

Therefore :

All power wires should be selected in the category : M2

All equipment should be built in such a way that no spark may start a fire.

Any equipment not specifically designed for use in compressed air should be validated by a competent person who will assess the risk of bursting a fire during normal use and in case of breakdown (fail safe).

A simple means to prevent dangerous, sparks is to select electrical equipment with CE marks showing it is acceptable for use in flammable or explosive atmosphere (CEN Electric devices, explosive atmospheres, 94/9/CE, dated 23 March 1994,

* **Plumbing**

Regular piping should be in agreement with pressure vessels systems rules.

Oxygen and gases with high oxygen concentration ($FO_2 > 0.25$) circuits, require special precautions (reduce pressure as much as practicable in all distribution lines, all equipment must be oxygen compatible and internally cleaned by a competent person on installation). No ball valve should be used to operate oxygen circuits. All gas storage area should be properly ventilated or equipped with a leakage alarm (high oxygen content).

Connecting oxygen cylinders to the circuit should be made only by qualified personnel.

*** Measurements, analysis, recorders ...**

Calibration of meters is part of the maintenance program. It should be done at regular intervals and logged into the maintenance register.

Pressure profiles and oxygen content of the atmosphere should be recorded

*** Fire fighting systems**

Internal fire fighting system includes : A manual extinguishing system operable by the attendant, a sprinkler type water deluge triggered independently from inside or outside. Override valves (inside and outside) should be available to prevent flooding when fire is eventually under control.

It is part of fire prevention to be able to decompress quickly the chamber for evacuation and at the same to cool efficiently the burning material and reduce immediately the partial pressure of oxygen closer to 0.2 bar. A fast decompression valve operable from outside at the attendant position, eventually sealed with a safety breakable thread, is a strong recommendation.

*** Breathing masks**

In case of fire it is extremely important that any extra oxygen input in the atmosphere should be stopped, and that breathing masks be available for all. Shifting HBO masks to air will cover the need for the patients; extra masks should be available, one for each attendant eventually present in the chamber.

Very little can be done to protect hoses delivering gases to the masks, they should be built in heat and fire resistant material, the deluge system is intended to protect them until evacuation can be carried out.

*** Lock attendant station**

A special care should be given by the manufacturer of the system to make the control of the chambers easy and fool proof. Proper markings are needed showing gas circuits and functions of valves as well as their position. When video screen are used, their location and brightness should be controlled. Communication system should have a back-up arrangement, and the quality of microphones and speakers in the chambers should be of good quality, a permanent listening capability for the lock attendant is needed. A telephone line in connection with the telephone control panel of the building should be available at the position of the lock attendant

Noise level due to decompression of gases should be removed from the place by proper piping and silencers.

3.2 - Construction of buildings

* Patients access

In addition to the access to the chamber some care should be given in the room available for patient preparation, inspection and handling around the installation in particular when intensive care patients are concerned.

* Connection with hospital

Many of the indications of HBO are for intensive care patients, who require special equipment and transport from the hospital, a close connection with the hospital is a must for Hyperbaric Centres accepting intensive care indications. This includes laboratories and medical analysis capabilities.

* Fire precautions

The hazard of fire in the Hyperbaric, facility are related to gas storage, oxygen circuits, pressure vessels and the fact that for some indications decompression of patients for evacuation may be fatal to the patient (arterial embolism, DCI, some CO poisoning cases ...). And it also may be dangerous for the attendant involved in such cases.

A contingency plan should be prepared with the fire brigade to take into account those specific hazards and organize fire fighting procedure accordingly.

All markings in relation with fire fighting and evacuation must be displayed

* Gas storage, compressors room, distribution plumbing...

It is of primary importance that, in all situations, pressure could be maintained in the chamber and that ventilation should not be interrupted for more than a few minutes. The gas supply system should be so arranged that in case of failure (compressor, electricity, cooling water, piping breaks ...) a back up system become operational at once to match the gas requirements for the treatment and the possible required decompression of personnel. This can be achieved via gas storage, emergency compressors, emergency electric supply... A document should demonstrate the risk assessment, which leads to the choice of an adapted solution. The corresponding emergency procedure should be in writing and should be part of the training of the personnel in charge.

* Equipment authorized for use under pressure

The equipment permanently used in the chamber and designated for use under pressure should be devoted to that activity and be clearly identified. It should have been evaluated for suitability of the purpose either by the initial manufacturer of the chamber or jointly by the user and the manufacturer of the equipment.

A list of those equipments should be part of the safety manual. Example: hospital wheel chairs should be greased with non burning grease, private wheel chairs have to be left outside, ...

Any new item to be entered into the chamber should be controlled by a competent person who will sign an authorization to use under pressure, eventually in association with special recommendations or safety rules when applicable and after questioning the manufacturer.

3.3 - Maintenance Program

*** Schedule for maintenance operations**

In the instruction manual provided by the manufacturer of the installation, there should be proper guidelines for the maintenance schedule. The manager of the installation will formalize the maintenance program in the safety manual.

In particular only products and spare parts recommended by the manufacturer should be used (oxygen compatible lubricants for example).

*** Air quality controls.**

The frequency of air quality controls is depending of the type of compressors used, the type of filtering units and the activity of the centre. This should be defined in agreement with the guidelines given by the manufacturer(s) of the gas production plant and incorporated into in the safety manual.

*** Maintenance logging**

All maintenance operations carried out by technicians should be logged in the maintenance register and signed by the technician in charge.

Entries should be left open for the personnel to report on day-to-day breakdowns and remedial actions taken.

*** Emergency drills**

The manager of the installation should recommend safety drills, mostly oriented towards fire prevention and fire fighting, all personnel should participate to those safety drills, which should also be logged in the operation log-book.

4 - OPERATIONS

4.1 - Staffing

*** Number and role of persons**

During any treatment the functions involved are :

- Supervision of the treatment (medical aspect and safety of operations),
- Operation of the chambers,
- Attendance of patients under pressure,
- Emergency assistance under pressure if needed

Depending on the type of centre, the number of simultaneous use of pressure chamber the minimum team staffing is variable. There should be a minimum of 3 qualified persons outside (Supervision, lock attendant and emergency help).

Any staff member accepted for compression should be medically fit to undergo pressurization.

*** Under pressure patients attending policy**

It is presently a common practice in several hyperbaric units not to attend walk-in patients for the whole session, the attendant being locked out after compression or even not being compressed at all when patients have experience of the exposure

The policy on patient attending under pressure should also be clearly defined in the safety manual. Instructions to un-attended patients should be sufficient for them to face minor problems under pressure and to control properly oxygen mask leakage (both ways).

4.2 - Patient preparation / control

*** Information to the patients**

The content and the procedure of information to the patients should be clearly established, eventually with a specific leaflet or document to be given to the patients, on the occasion of exposures. Who is in charge of this information and copies of the documents are to be included in the safety manual.

*** Medical preparation**

Before entering the chamber, all patients should be controlled to assess their medical situation, in particular when they are connected to medical devices or when they were dressings on wounds ...

*** Practical preparation**

Policy concerning patients clothing, bedding equipment, inspection of personal items is needed, A recommendation should be that patients keep a minimum of personal clothes and receive at least a blouse covering the remaining clothes. That blouse being made out of low flammability material (cotton). Consequently a personal items storage look should be made available for each patient.

5-CONCLUSION

Basically there are few construction problems left when the manufacturer of the HBO facility is safety conscious and the buyer ready to invest in a safe system. Most of the safety problems in HBO are related to the procedures used and the precautions enforced during the day-to-day work.

These precautions are directly under the control of the personnel. The personnel should be well aware of the centre safety policy; he (she) should have received the initial training, a copy of the safety manual and be given a clear definition of his (her) responsibilities during the sessions.

The management, after establishing that policy in a safety manual, should also make sure it is properly applied. This needs personal involvement and frequent controls.