



THE BRITISH HYPERBARIC ASSOCIATION

**HEALTH & SAFETY FOR
THERAPEUTIC HYPERBARIC
FACILITIES:**

A CODE OF PRACTICE

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The document draws heavily, both in wording and format, on the "Cox Report" and the Approved Codes of Practice for the 1998 Diving at Work Regulations. Several individuals, who were not part of the original working party, made substantial contributions to the text, editorial process, or the provision of meeting facilities: specific thanks go to Dr. Steve Doherty, Mr. David Head and Ms. F. Hirst of the HSE, Mr D. Elner of DERA, and Dr. A. Pitkin of INM.

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*Jon Broome
Chairman, BHA Health & Safety working Party*

HEALTH & SAFETY FOR THERAPEUTIC HYPERBARIC FACILITIES: A CODE OF PRACTICE

FOREWORD

Therapeutic hyperbaric facilities are usually complex, operated by a multi-disciplinary team and use a method of treatment which has unique physical hazards in addition to the usual risks of medical therapy. Thus within therapeutic hyperbaric units the management of safety and health is of paramount importance. This should include careful risk assessment, supervision and control of all operations by competent personnel, implementation and review of safe systems of work and particular reference to information, instruction and training of all staff.

This Code gives practical guidance on the safe operation of therapeutic hyperbaric facilities for British Hyperbaric Association members who currently represent those providing therapeutic hyperbaric care to the National Health Service. It is thus intended for use by the Department of Health & National Health Service management, Health Authorities, Hyperbaric Therapy Providers, Hyperbaric Unit Medical Directors and all who may require to purchase or provide therapeutic hyperbaric care. Although primarily intended for use within the United Kingdom, it may be of some value to those elsewhere.

The Code has been written with the intention of being goal setting rather than prescriptive. This has the advantage that as health and safety legislation evolves then hyperbaric therapy providers will be able to adapt and utilise good standards and practices without necessarily making this Code redundant.

The British Hyperbaric Association believes that this code provides a useful basis on which to build good health and safety practice within therapeutic hyperbaric facilities. It has undergone widespread consultation within the BHA including all hyperbaric facility Medical Directors and the Health and Safety Executive.

As Chairman it is most satisfying to write this Foreword for what should be an important step forward in safety and health for the practice of hyperbaric medicine in the United Kingdom.



Dr. A P. Colvin
Chairman, British Hyperbaric Association

HEALTH AND SAFETY FOR THERAPEUTIC HYPERBARIC FACILITIES: A CODE OF PRACTICE

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HEALTH AND SAFETY FOR THERAPEUTIC HYPERBARIC FACILITIES: A CODE OF PRACTICE

1. INTRODUCTION

1.1 Explanation and Intention of the Code

This Code is goal setting and is intended to enable different Therapeutic Hyperbaric Facilities to adapt and use existing good standards and practices to meet the requirements of existing Health and Safety legislation. The guidance in the Code relates to the safety of personnel working in or adjacent to the hyperbaric facility, and to others who may be affected by the operation of the facility. It does not relate to the medical treatment procedures used for the management of patients unless these procedures have potential impact on patient safety or the health of others.

1.2 Official Status of the Code

The British Hyperbaric Association (BHA) has compiled and issued this booklet with advice from the Health and Safety Executive. The guidance advises specifically on the application of British health and safety legislation to those providing hyperbaric treatment; it is intended to assist BHA members and others in meeting their duties under health and safety legislation. The guidance is aimed at all those involved in providing hyperbaric treatment, including employers, managers and clinicians. It may also be of use to employees and their representatives with regard to the current standards for the safe operation and use of hyperbaric facilities.

Although this Code does not have the same legal status as an Approved Code of Practice, Health and Safety Inspectors may refer to it as illustrating good practice.

1.3 Who Wrote the Code

The Health and Safety Committee of the BHA wrote the Code.

1.4 Scope and Areas Covered by the Code

The Code applies to all therapeutic hyperbaric facilities that provide recompression or hyperbaric oxygen therapy, either emergency or elective, to patients. It does not apply to facilities operated by Diving Contractors as a requirement of the Diving at Work Regulations (DWR) 1997, solely for the treatment of divers employed by the contractor, except where such facilities are also operated as a medical facility for other patients. Similarly, the Code does not apply to facilities operating under the Compressed Air regulations 1996. The Code covers all therapeutic hyperbaric facilities operated in the United Kingdom by BHA members.

Under this Code, guidance for ensuring the health and safety of patients undergoing hyperbaric treatment should also apply to human subjects in physiological experiments involving hyperbaric exposure

1.5 Sources of Information (See Annex C)

1.6 Historical Background

Hyperbaric chambers were originally established on a wide scale for the treatment of decompression illness and the bulk of chambers remain solely or principally to support diving activities or compressed air tunnelling. Hyperbaric oxygen treatment is, however, also used for medical treatments unrelated to decompression illness and there are several conditions for which it is generally accepted as being helpful. These are specified in the European Committee for Hyperbaric Medicine Consensus document (See Annex C) and in Undersea and Hyperbaric Medical Society Hyperbaric Oxygen Committee Reports (See Annex C). Both these documents are subject to periodic update.

The Faculty of Occupational Medicine of the Royal College of Physicians set up a Working Party in 1991 under the chairmanship of Professor R I McCallum to examine the minimum acceptable standards of patient care, medical supervision and general safety of hyperbaric chambers using compressed gases in medical treatment. The deliberations of this initial Working Party were discussed widely and as a result of its report, a second Working Party under the chairmanship of Dr R A F Cox, Vice-Dean of the Faculty, was established with the remit to produce a Code of Good Working Practice for the Operation and Staffing of Hyperbaric Chambers for Therapeutic Purposes. This report was accepted by the British Hyperbaric Association and was published by the faculty of Occupational Medicine in May 1994. The "Cox Report" report categorised therapeutic hyperbaric chambers into four categories, which are redefined in the following section.

1.7 Categories of Chambers

Category 1 (Multiplace) Chambers - Comprehensive hyperbaric facilities capable of supporting the treatment of patients who are critically ill, from any cause, and who may require hyperbaric intensive care.

Category 2 (Multiplace) Chambers - Facilities capable of receiving elective *or* emergency referrals for any accepted application of hyperbaric oxygen therapy, but excluding patients who are critically ill at the time of referral or are considered likely to become so.

Category 3 (Multiplace) Chambers - Facilities without some of the capabilities of Categories 1 or 2, which are sited specifically to support diving projects (either commercial or recreational) and work in compressed air. These facilities should also be capable of providing elective treatment of residual symptoms of decompression illness.

Category 4 (Monoplace) Chambers - Facilities operating at relatively low pressure and without an air-lock capability. The expectation is that such

chambers providing a treatment service on behalf of the NHS or the private health care sector would normally be sited within the boundaries of, or in very close proximity to, a hospital. These facilities should be capable of receiving elective and emergency referrals of patients in any diagnostic category where the Medical Director or Hyperbaric Duty Doctor supervising the treatment judges that a requirement to have access to the patient during hyperbaric treatment is unlikely. Normally monoplace chambers are not suitable for the immediate treatment of acute decompression illness.

All therapeutic hyperbaric facilities in any of the above categories must have buildings, plant and equipment, and administration and organisational structures that are "fit for purpose". To that end, therapeutic hyperbaric facilities of all categories must conduct a hazard and risk assessment of the working environment. This assessment should be documented and made accessible to hyperbaric facility staff by incorporation in a manual of Standard Operating Procedures or equivalent.

2. DEFINITIONS

2.1.1 A **therapeutic hyperbaric chamber** is a pressure vessel capable of accommodating one or more persons with the purpose of providing medical treatment. Therapeutic hyperbaric chambers may be *multiplace* or *monoplace*. Multiplace chambers are larger structures intended to hold two or more persons (including the attendant(s) for medical treatments); they may have two or more compartments to allow access and egress of medical staff and equipment while maintaining pressure. They are usually pressurised with air or a helium/oxygen mixture. Monoplace chambers are smaller, single compartment structures in which a patient (normally in a seated or recumbent position) is observed by the attendant from outside the chamber. Monoplace facilities usually operate at relatively low pressure and are normally pressurised with oxygen or air.

2.1.2 For the purposes of this Code, **chamber compression** is defined as a period of increased pressure within a therapeutic hyperbaric chamber of greater than 100 mB (10kPa) above ambient atmospheric pressure for the purposes of treatment, trials, training or testing.

2.1.3 A **therapeutic hyperbaric facility** consists of the therapeutic hyperbaric chamber(s) together with associated plant and buildings, staff (both technical and medical), and a specific administrative organisation.

2.1.4 Under this Code, a **patient** is any person suffering from a medical condition or injury, who occupies a therapeutic hyperbaric chamber during chamber compression with the purpose of altering the natural course of their medical condition or injury. Different gas mixtures, including compressed air, may be breathed by the patient during their occupancy of the chamber. This definition of a patient includes persons with radiation tissue injury or any other condition who receive *prophylactic* hyperbaric oxygen prior to surgery, and persons who are control subjects in therapeutic trials of hyperbaric therapy.

2.1.5 **Hyperbaric treatment** is defined as period of increased pressure to greater than 100 mB (10kPa) above ambient atmospheric pressure, within a therapeutic hyperbaric chamber, for the purposes of treatment of a patient, as defined above.

2.1.6 The **hyperbaric treatment team** consists of all medical and technical personnel directly involved with the hyperbaric treatment of a patient.

3. BACKGROUND

Legal requirements

British health and safety legislation gives responsibility for health and safety to those who create, manage and work with risks related to employment. This is achieved through the Health and Safety at Work etc. Act 1974, which places a duty on all employers to ensure, so far as is reasonably practicable, the health safety and welfare at work of all their employees and those not in their employment. It further defines that duty in particular to "the provision of such information, instruction, training and supervision as is necessary to ensure so far as reasonably practicable, the health and safety at work of employees". The Act also places duties on self employed people, employees and certain individuals such as directors and managers.

The Management of Health and Safety at Work (Amendment) Regulations 1994 specifically refer to compressed air work and relates this to the health and safety of pregnant mothers, but the Diving at Work Regulations 1997 and the Work in Compressed Air Regulations 1996 both exclude medical workers using compression chambers for therapeutic purposes from their requirements. Nonetheless, most other health and safety legislation, such as the Noise at Work Regulations 1989, the Manual Handling Operations Regulations 1992, the Confined Spaces Regulations 1997 and the Pressure Systems Regulations and Transportable Gas Containers Regulations 1989 (this set of Regulations is due to be replaced in the near future by the Pressure Systems Safety Regulations) applies to hyperbaric health care workers in the same way as it applies to other employees (See Annex C)

4. STAFFING AND SAFE WORKING PRACTICES

4.1 **Standard Operating Procedures**

Each therapeutic hyperbaric facility should develop its own **Standard Operating Procedures (SOPs)**, which document the detailed working practice for all anticipated activities within the facility. SOPs should contain all such information and instructions as are necessary, including emergency procedures and contingency plans, to give advice, to guide, or to regulate the behaviour of those taking part in the functioning of the facility, either in a medical or technical capacity. SOPs should be reviewed periodically and updated as appropriate when conditions change.

All staff should possess or have immediate access to a copy of the SOPs, and be familiar with the guidance contained therein, relevant to their position.

4.2 Staff Competencies

Competence can be based on training and assessment and/or experience. However as no two therapeutic hyperbaric facilities are likely to be the same a period of familiarisation and induction training will be required within individual hyperbaric facilities.

Personnel currently employed in therapeutic hyperbaric facilities in Britain come from a variety of occupational backgrounds and have largely acquired their knowledge without the benefit of formal training. Such training in the various clinical and technical skills required for the safe operation of a therapeutic hyperbaric facility is in its infancy in Great Britain. The Code acknowledges this, and also recognises that different facilities may use their staff in different ways, with different individual competency requirements. Nonetheless, all staff must be competent to do the work expected of them and, ultimately, the responsibility for assessing competence of a member of the hyperbaric treatment team lies with the Hyperbaric Therapy Provider. Therefore, clear roles and responsibilities need to be defined and recorded on appointment or promotion of staff. The following scheme may be used for guidance.

4.2.1 The **Medical Director** should be a registered medical practitioner; a postgraduate qualification in a relevant speciality is an advantage. He/she should have practical experience and be competent in all medical aspects of therapeutic hyperbaric facility activities. His/her competence will be consistent with the types of patients accepted for treatment by the facility in which he/she works.

4.2.2 The **Hyperbaric Duty Doctor** will be expected to acquire experience and training while in post. He/she should only be allowed to work unsupervised by his/her medical director once he/she has demonstrated his/her competence in a range of standard treatments. Arrangements should be made to ensure that he/she has access to advice and assistance from a more senior colleague when working unsupervised. He should normally be passed medically fit to work under pressure.

4.2.3 Only the Hyperbaric Therapy Provider can appoint a **Supervising Chamber Operator** and this must be done in writing. No formal qualification currently exists. There are a number of people who have formal training in the operation of hyperbaric chambers but for different operational circumstances i.e. diving and work in compressed air. For the immediate future on site training from scratch or based on previous experience will be the norm. for Supervising Chamber Operators in the context of therapeutic hyperbaric facilities.

When considering competence of a candidate for a Supervising Chamber Operator's position, the Hyperbaric Therapy Provider should consider the candidate's technical knowledge, experience, practical attributes, reliability, ability to conduct hyperbaric treatments in a safe manner in the context of the specific technical demands of the pressure system and intended clinical activities; ability to manage members of the Hyperbaric Treatment Team appropriately; ability to react appropriately in the presence of patients; ability to act sensibly in an emergency.

The Hyperbaric Therapy Provider should not assume that the candidate is competent. The Hyperbaric Therapy Provider will be in a good position to decide on the candidate's competence if the candidate has worked for the company previously or for some time in another capacity. If the Hyperbaric Therapy Provider does not know the candidate, it will be necessary to make appropriate enquiries concerning experience. Any limitations to the competence of an appointed Supervising Chamber Operator should be documented (e.g. "Not competent to supervise saturation decompressions").

Unless they are expected to enter the hyperbaric chamber while pressurised, Supervising Chamber Operators do not need to have a certificate of medical fitness for hyperbaric exposure, but they must be competent to manage the technical aspects of a medical emergency in the chamber from the outside. Supervising Chamber Operators must be medically fit to discharge their responsibilities and should not suffer from a medical condition that could be judged, with reasonable foresight, to jeopardise the safety of patients or staff (e.g. risk of sudden incapacitation).

4.2.4 The **Chamber Attendant** (who may be a medical, nursing or technical staff member), must have a certificate of medical fitness for hyperbaric exposure. They should be competent in the observational, medical and technical procedures consistent with safe chamber operation and delivery of a satisfactory standard of in-chamber care to the types of patients accepted for treatment by the facility in which he/she works. These competencies should include safe patient handling and moving techniques and first aid. For acutely ill patients, competence in intensive care techniques and Advanced Life Support will be required. All staff who may be the sole in-chamber attendant during the hyperbaric treatment of a patient must be competent to deliver Basic Life Support.

4.2.5 The **Monoplace Attendant** should be competent in the operation and patient care techniques required for safe treatment of patients in monoplace chambers. Monoplace chamber attendants must be trained in Basic Life Support and have immediate access to medical and/or nursing staff competent in delivering Advanced Life Support.

4.2.6 **Engineering and technical staff** should be competent to maintain the mechanical and electrical equipment for which they are deemed responsible, including the construction and layout of the therapeutic hyperbaric facility, and the high and low pressure gas systems. They should be aware of the relevant legal requirements.

4.3 Personnel and Responsibilities

Different therapeutic hyperbaric facilities may utilise their staff in different ways and a rigid scheme that allocates or delegates fixed responsibilities to all individual classes of personnel is inappropriate. However, the responsibilities of the **Hyperbaric Therapy Provider** and **Supervising Chamber Operator** are fundamental to the concept of this Code and are defined in detail below.

In general, each therapeutic hyperbaric facility must define its own division of responsibilities or Terms of Reference for both medical and technical staff, and record

this information in the therapeutic hyperbaric facility's administrative documentation (normally incorporated within the SOPs). A statement naming the person with overall responsibility for therapeutic hyperbaric facility activities, and the person(s) with delegated responsibility for medical patient care, non-clinical administration, and health and safety for the facility, should be included (see below). The lists provided in the following sections are given as a guide and are not intended to be comprehensive. A varying range of other clinical and support services may be involved in therapeutic hyperbaric facility activities:

4.3.1 Hyperbaric Therapy Provider

For every therapeutic hyperbaric chamber there shall be one person and one person only who is nominated as the Hyperbaric Therapy Provider, and who is in overall administrative control of the therapeutic hyperbaric facility. The hyperbaric therapy provider need not have a technical or medical role in the actual provision of hyperbaric treatment.

The hyperbaric therapy provider is the person who either:

- a. employs or contracts the technical and medical personnel engaged in hyperbaric treatment of patients; or
- b. as a self-employed person, may personally provide medical and/or technical support to the hyperbaric treatment of patients.

Where there is more than one person or organisation falling within sub-paragraphs a. or b. above, those persons shall jointly appoint in writing one of themselves to act as Hyperbaric Therapy Provider.

The Hyperbaric Therapy Provider shall ensure, so far as is reasonably practicable, that the operation of the therapeutic hyperbaric facility is planned, managed and conducted in a manner which protects the health and safety of all persons involved, including patients, effected by operation of the therapeutic hyperbaric facility. This responsibility is distinct from the professional medical responsibility for the clinical care of patients, which may be delegated to the Medical Director of the therapeutic hyperbaric facility, or the hospital consultant in clinical charge of the case. However, in some therapeutic hyperbaric facilities the overall responsibility of the Hyperbaric Therapy Provider and clinical responsibilities of the Medical Director (see below) may be borne by a single person.

Each Hyperbaric Therapy Provider shall ensure that a record containing the required particulars (see documentation annex a) is kept either in documentary or electronically retrievable form, for each hyperbaric treatment.

The **Hyperbaric Therapy Provider's** general health and safety responsibilities are ensure that:

- a. risk assessments have been carried out for all foreseeable technical or administrative aspects of therapeutic hyperbaric facility operation;

- b. there are sufficient personnel available in the Hyperbaric Treatment Team to provide adequate patient safety and safe technical operation of the chamber during a hyperbaric treatment. (see section on Hyperbaric Treatment Team and Associated Working Practice);
- c. the personnel in the Hyperbaric Treatment Team are competent;
- d. sufficient plant and equipment is provided for safe technical chamber operation and that it is fit for purpose, correctly certified and maintained (see sections on Equipment and Maintenance);
- e. medical equipment for use in the hyperbaric environment is sufficient, appropriately maintained, correctly certified, and fit for purpose, as advised by the medical director of the therapeutic hyperbaric facility;
- f. written Standard Operating Procedures (SOPs) are available, which include treatment protocols for guidance, and procedures for both medical and technical emergencies and contingency plans. The Standard Operating Procedures should be signed and dated by the Hyperbaric Therapy Provider;
- g. the Medical Director, Hyperbaric Facility Manager, and Supervising Chamber Operators are appointed in writing and the extent of their delegated responsibility is documented;
- h. there is a clear reporting and responsibility structure laid out in writing;
- i. there is appropriate occupational health provision for staff; and
- j. all other relevant legal requirements are complied with.

4.3.2 The **Medical Director** is responsible for:

- a. direction of clinical activities of the facility;
- b. production of clinical assessment and treatment protocols;
- c. appointment and/or delegation of clinical staff;
- d. supervision of all clinical staff;
- e. general medico-legal responsibility for the facility;
- f. safe custody and confidentiality of clinical records;
- g. the work of other medical staff if unsupported; and
- h. advising on staff health and safety.

4.3.3 The **Hyperbaric Duty Doctor**, (who may also be the Medical Director) is responsible for:

- a. general medical support;
- b. examination of patients, recording of findings;

- c. prescription of hyperbaric treatments and other therapy as required;
- d. discharge and onward patient referral; and
- e. advice on and the safe operation of medical equipment.

4.3.4 The **Hyperbaric Facility Manager** is responsible to the Hyperbaric Therapy Provider for:

- a. general administration and personnel management for the facility;
- b. overall supervision of all technical, maintenance and administrative staff;
- c. the work of technical, maintenance and administrative staff, if unsupported; and
- d. health and safety aspects of all facility plant, equipment and buildings, including risk assessments and audit.

4.3.5 The **Supervising Chamber Operator** is responsible to the Hyperbaric Facility Manager for:

- a. direct supervision of pressure system operations;
- b. the safety of the chamber and its occupants under his direct supervision;
- c. minor maintenance; and
- d. direction and supervision of other technical and maintenance personnel.

The Supervising Chamber Operator shall ensure that the hyperbaric treatment he is supervising is carried out, so far as is reasonably practicable, without risk to the health and safety of all those taking part in the hyperbaric treatment and of other persons who may be affected thereby. They are not responsible for risks to health of patients that may arise specifically because of the patient's medical condition or its interaction with the hyperbaric environment; this is the responsibility of the Medical Director.

The Supervising Chamber Operator with responsibility for the hyperbaric treatment is the only person who can order the start of compression, and must be in control of the technical aspects of chamber operation at all times. Supervising Chamber Operators can only supervise that part of a therapeutic hyperbaric facility that they can personally control, both during routine procedures and in an emergency. For large chamber complexes, or treatments involving saturation decompression, more than one Supervising Chamber Operator may be needed. Supervising Chamber Operators should only hand over supervisory control to another suitably qualified Supervising Chamber Operator. Such a transfer of responsibility will need to be entered in the hyperbaric treatment record.

The Supervising Chamber Operator is entitled to give such reasonable instructions in relation to the safety of any person taking part in the hyperbaric treatment as are necessary to comply with this Code. Normally, this would be done in consultation with the Medical Director or Hyperbaric Duty Doctor. Such orders could include instructing unnecessary personnel to leave a control area or instructing personnel, including competent nursing personnel, to operate equipment.

In an emergency, the Supervising Chamber Operator may accept responsibility for acting independently in the interests of safety, without necessarily first referring to the

Hyperbaric Duty Doctor. The Medical Director or Hyperbaric Duty Doctor can instruct the Supervising Chamber Operator to terminate or modify a hyperbaric treatment for patient safety or medical reasons.

To ensure that a hyperbaric treatment is carried out safely, Supervising Chamber Operators will need to:

- a. satisfy the Hyperbaric Therapy Provider that they are qualified and competent to carry out the work and that they understand their own areas and levels of responsibility and who is responsible for any other relevant areas. Such responsibilities will need to be specified in writing by the Hyperbaric Therapy Provider; and further training provided if necessary.
- b. satisfy themselves that the personnel under their supervision are competent to carry out the work required of them. They should also check, taking advice from the Medical Director or Hyperbaric Duty doctor if appropriate, that as far as can reasonably be ascertained, that personnel who are to be in a hyperbaric chamber under pressure are medically fit;
- c. ensure, as far as is reasonably practicable, that equipment intended for use during any particular hyperbaric treatment is adequate, safe, properly certified and maintained, and is checked by them or another competent person prior to being pressurised, this includes items to be locked in after the hyperbaric chamber has been pressurised. Such checks should be documented, for example on a pre-prepared checklist, and recorded in the hyperbaric treatment record;
- d. ensure that the risks from physical hazards of the hyperbaric environment, are assessed and fully understood by all parties and that, if required, training is given and suitable precautions are taken. Where possible infectious hazards arise from individual patients, advice on appropriate precautions should be sought from the Medical Director or other competent person;
- e. ensure, as far as is reasonably practicable, that the operation that they are being asked to supervise complies with the requirements of this Code;
- f. establish that all relevant people are aware that a hyperbaric treatment is going to start or continue; and
- g. have clear audible and visual communications with personnel under their supervision in the chamber. So long as they have such communications they do not need to be able to operate physically every control under their responsibility. For example, a Supervising Chamber Operator will be able to supervise adequately the operation of Built in Breathing System (BIBS) even though he has no direct physical control over these parts of the system inside the hyperbaric chamber.

4.3.6 The **Assistant Chamber Operator** is responsible to the Supervising Chamber Operator for aspects of the safe operation of the chamber system, as directed.

4.3.7 The **Chamber Attendant** is responsible to the Duty Hyperbaric Doctor for:

- a. direct care of the patient(s) inside the chamber;
- b. implementing the decisions of medical and supervising staff outside the chamber; and
- c. safe operation of medical equipment.

4.3.8 The **Monoplace Attendant who may also be the Supervising Chamber Operator** is responsible to the duty Clinical Director for:

- a. the safe operation of the pressure system;
- b. direct care of the patient outside the chamber;
- c. indirect care of the patient inside the chamber;
- d. record keeping and minor maintenance, and
- e. the monoplace attendant may also be the supervising chamber operator.

4.3.9 **Nursing Staff, who may also be chamber attendants**, are responsible to the Duty Hyperbaric Doctor for:

- a. general nursing care of the patient;
- b. advising on nursing matters;
- c. provision of support to relatives;
- d. acting as patient advocate where appropriate; and
- e. safe operation of medical equipment.

4.3.10 **Engineering and Technical Staff** are responsible to the Hyperbaric Facility Manager for maintenance and repair of the pressure system and other equipment in accordance with laid down procedures.

4.3.11 **Hyperbaric Therapy Providers** may appoint a **Safety Director**, who has delegated responsibility for all non-clinical aspects of health and safety related to the technical and administrative operation of the therapeutic hyperbaric facility.

4.4 Hyperbaric Treatment Teams and Associated Working Practice

4.4.1 Each Hyperbaric Treatment Provider shall ensure that there is sufficient staff with suitable competence to operate the therapeutic hyperbaric chamber and associated equipment and to provide appropriate medical support. Staffing levels will be adequate to carry out safely and without risk to health both the hyperbaric treatment and any action necessary in the event of a reasonably foreseeable emergency connected with the hyperbaric treatment. These staff comprise the **Hyperbaric Treatment Team**.

The Hyperbaric Therapy Provider should specify the size and make-up of the **Hyperbaric Treatment Team** to be involved in the various types of hyperbaric treatment anticipated by the treatment facility, based on the category of the facility and the numbers and types of patients. Issues to be considered will include the availability of medical staff, the number of in-chamber attendants and support personnel, their grades, competence and qualifications, and their ability to run the hyperbaric treatment safely, and to carry out contingency and emergency plans.

4.4.2 Minimum Team Size

The minimum team size normally required to be present on site to conduct a safe hyperbaric treatment within the scope of this Code is three for a multiplace chamber (Hyperbaric Duty Doctor, Supervising Chamber Operator, Chamber Attendant) , and two for a monoplace chamber (Hyperbaric Duty Doctor, Monoplace Attendant). A team member available to provide emergency technical support is desirable, and additional personnel may be needed to provide adequate medical care to critically ill patients, or to assist in an emergency. Actual team sizes will depend on Risk Assessment and the multi-role abilities of available staff. The need for comfort breaks must also be considered.

4.4.3 Number of Chamber Attendants

The required number of attendants will depend on the numbers and types of patients to undergo each type of hyperbaric treatment and the appropriate competencies and number of personnel required for safety and adequate care of the patient(s). Where staff members are in-chamber attendants for more than one treatment per day, facility policy or a prior risk assessment should take into account the number of hours to be worked each day, the type of pressure exposure, and any decompression requirements or modifications needed to ensure the safety of exposed staff.

Attendants may carry out other tasks, such as nursing duties, or act as Assistant Chamber Operators. or perform maintenance or engineering tasks provided that they are competent for such duties.

4.4.4 Over-lapping Functions

Individuals in a Hyperbaric Treatment Team may carry out more than one duty, provided that they are qualified and or competent to do so and that their different duties do not interfere with each other or affect the safety of other therapeutic hyperbaric facility personnel or patients.

4.4.5 Personnel not employed by the Hyperbaric Therapy Provider

Personnel who are not employed by the Hyperbaric Therapy Provider will need to be carefully considered for competence, suitability, and, where required, medical fitness for hyperbaric exposure before being included in the Hyperbaric Treatment Team. Such personnel can create a hazard if they lack familiarity with the procedures, rules and equipment.

4.5 Medical Fitness and Health Surveillance of Staff

4.5.1 Pre-employment

Both technical and medical staff of a therapeutic hyperbaric facility, who may be exposed to increased pressure as part of their job, should undergo initial and periodic medical screening to ensure that hyperbaric exposure will not precipitate or aggravate any medical condition.

Also for consideration, are the medical fitness standards required of both chamber supervisory staff and attendants in the chamber under pressure (e.g. where the incapacitation of key personnel may put the safety of patients at risk.)

4.5.2 Day-to-day fitness: Staff Responsibilities

Even a minor illness, such as the common cold or a dental problem, can have serious effects under pressure. No therapeutic hyperbaric facility staff member should be exposed to chamber compression if he/she knows of any illness or medical condition that makes him/her unfit for hyperbaric exposure. Staff members who consider themselves unfit for any reason have a duty to report their concerns to the Supervising Chamber Operator before the start of chamber compression. Supervising Chamber Operators should seek guidance from the Medical Director, Hyperbaric Duty Doctor, or seek other competent medical opinion if there is doubt about a staff member's medical fitness for compression.

4.5.3 Reporting Of Work-Related Illness In Staff

The occurrence of significant decompression sickness (DCS) and barotrauma resulting in lung or other organ damage should be reported under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations (RIDDOR). Staff who suffer an incident of DCS or barotrauma requiring treatment will need to record details of it and of the treatment that they received in their logbooks. The Medical Director or other competent doctor is required to review the staff member's fitness to return to work under hyperbaric conditions, and record a statement of hyperbaric fitness in the individual's log book. The circumstances that led to the incident must be reviewed and, if appropriate, the Standard Operating Procedures amended to reduce the risk of a recurrence. The Supervising Chamber Operator responsible for the staff member's first pressure exposure after treatment will need to sight the statement of fitness in the individual's log book before commencing the exposure.

4.5.4 Certification of Medical Fitness

All hyperbaric facility staff members who may routinely be exposed to increased pressure should possess a valid "certificate of medical fitness for hyperbaric exposure" following a medical examination performed by a medical practitioner with the necessary competence. The examining medical practitioner should meet the knowledge and experience criteria required of an HSE approved "medical examiner of divers".

The medical examination should result in the issue of a written statement or certificate which confirms the staff member's medical fitness for hyperbaric exposure to work in the confines of a dry therapeutic hyperbaric chamber during chamber compression. Certification of fitness is valid for as long as the medical practitioner certifies, up to a

recommended maximum of 12 months. It should be renewed annually (or on expiry) if a staff member wishes to continue being exposed to hyperbaric conditions at work. This annual recertification process may be considered a form of health surveillance.

Trainee therapeutic hyperbaric facility staff should hold a certificate of medical fitness for hyperbaric exposure before they begin training. The pre-training medical examination should contain the same elements as the annual medical examination.

Specialist clinical staff, who are not primarily employees of the therapeutic hyperbaric facility, who might be called upon infrequently to provide in-chamber support for certain categories of patient, should be appropriately screened for medical fitness for hyperbaric exposure by the medical director or hyperbaric duty doctor immediately prior to being exposed to pressure.

Detailed guidance on medical standards for therapeutic hyperbaric facility staff may be found in the BHA publication *Medical Fitness Standards for Hyperbaric Health Care Workers: Guidelines for Examining Physicians and Hyperbaric Therapy Providers* (in preparation).

4.6 Risk Assessments

The Standard Operating Procedures shall contain site-specific risk assessments based on the hazards identified in the hyperbaric treatment facility.

Complete risk assessment should take place as laid down by the HSE in “*Five Steps to Risk Assessment*”, (INDG163[rev1]).

Step 1 Look for the hazards;

Step 2 Decide who might be harmed and how;

Step 3 Evaluate the risks and decide whether existing precautions are adequate or more should be done; (what control measures are in place? Are more needed?)

Step 4 Record your findings (if five or more persons are employed the risk assessments should be recorded); and

Step 5 Review your assessment and revise it if necessary.

A **hazard** is something with the potential to cause harm (this may include, by its very nature, the hyperbaric environment, other environmental factors, plant and equipment, and work organisation). A **risk** expresses the likelihood that the harm from a potential hazard is realised. The extent of the risk includes the numbers of people who might be affected by the risk, and the seriousness of the result if the risk is expressed. A risk therefore is the possibility that harm will occur and its nature and severity. These factors should be considered as part of the risk assessment.

4.6.1 Generic hazards in hyperbaric facilities

In a hyperbaric treatment facility, risks may arise from either medical, technical, mechanical, administrative, environmental or human factors related to the functioning of the facility. Where the risk cannot be eliminated completely, substitution of the existing arrangement by an alternative, safer, procedure or method should be considered. Where elimination of a hazard is not possible, the control measures and procedures to

minimise the risk should be defined and documented in the SOPs. Many factors need to be considered and it is not possible to provide an exhaustive list of hazards and risks in this code, but some examples of generic hazards found in therapeutic hyperbaric facilities are listed below:

- a. high pressures (risk of explosion, loss of pressure vessel integrity);
- b. oxygen (risk of ignition, cerebral and pulmonary toxicity);
- c. quality and quantity of breathing gas supply;
- d. adequacy and integrity of pressurised gas supply ;
- e. fire (procedures for prevention, suppression, and evacuation);
- f. electricity (electrical safety within the pressure vessel);
- g. prohibited materials within chamber (clothing, footwear, volatile/flammable substances, patients' effects, smoke contaminated clothing);
- h. volatile drugs (anaesthetic agents, allowable medical substances);
- i. pressure differentials (catheter / cannula cuffs & seals);
- j. pressure differentials (vascular lines);
- k. disposal of body fluids and waste;
- l. disposal of sharps and infected materials;
- m. hygiene and infection control, including measures if saturation decompression procedures are necessary (disinfection of masks, hoods, ventilators and associated equipment, MRSA policy, chamber disinfection);
- n. manual handling of patients on entry, exit to chamber and during treatment (use of slides, hoists and other patient handling aids);
- o. noise hazards and control measures (both for internal occupants of chambers and external staff);
- p. substances hazardous to health (disinfectants, lubricants etc.);
- q. staff health and safety, including medical surveillance and precautions against decompression illness in staff; and
- r. general and administrative hazards (display screen equipment, slip, trip, bump and fall hazards etc).

Risk assessments are required for a number of Health & safety regulations. Where a full Risk Assessment has been competently prepared and recorded under this Code for the technical, administrative and therapeutic aspects of a hyperbaric facility's operation, including specific hazards such as manual handling, noise, and hazardous substances, there should be no need to duplicate or conduct risk assessments under each regulation.

The Standard Operating Procedures will need to cover the general procedures for therapeutic hyperbaric chamber operation as well as hyperbaric treatment protocols. They will also need to provide contingency procedures for any reasonably foreseeable emergency (see below).

A clinical assessment of the risks and benefits of hyperbaric exposure specific to individual patients in the context of the disease processes or injuries from which they are suffering are the responsibility of the medical director; assessment of such clinical risks should not normally be included in the Standard Operating Procedures.

4.6.2 Specific hazards in hyperbaric facilities

A hyperbaric treatment requires a number of phases, which must be in the correct sequence. Some of these phases may be complex and involve technical as well as medical procedures which on their own do not present a hazard but in combination might. It is essential to take account of this potential problem when conducting the risk assessment.

4.6.3 Quantity of breathing gas

The quantities of gases needed for hyperbaric treatments need to be calculated and it must be ensured that sufficient supplies exist to complete the treatment and provide a reserve.

4.6.4 Noise

The operation of hyperbaric chambers is often inherently noisy. The noise hazard posed by various stages of therapeutic hyperbaric facility operation, both to inside occupants and external personnel needs to be assessed in accordance with the Noise at Work Regulations 1989. Where appropriate, reasonably practical preventive measures should be taken, otherwise protective procedures should be instituted. Health surveillance measures should be implemented if necessary.

4.6.5 Decompression sickness after hyperbaric treatment

Patients who have breathed oxygen during the majority of their hyperbaric treatment are unlikely to develop decompression illness, but the risk of pulmonary barotrauma is ever present, particularly in patients with lung disease. Attendant staff must be aware of the symptoms and signs and appropriate management should the sequelae of pulmonary barotrauma develop under pressure.

Attendant staff may breath compressed air during much of a hyperbaric treatment, and they are potentially at risk of decompression illness and barotrauma. Therapeutic hyperbaric facility staff should receive training in the recognition of decompression illness in themselves, and procedures should be in place to ensure the timely assessment and recompression treatment of any staff members who develop symptoms of decompression illness following attendance during a hyperbaric treatment. Restrictions on travel may be required.

4.6.6 Altitude changes after therapeutic hyperbaric exposure

Hyperbaric facility staff should be aware of the limitations on flying or travel in hilly or mountainous regions for a specified time after attending a hyperbaric treatment, depending on the pressure and length of exposure.

4.6.7 Oxygen toxicity

Cerebral oxygen toxicity is an inherent risk to both patients and attendants who breathe greatly increased partial pressures of oxygen during, or while decompressing from hyperbaric treatments. At 2.8ATA, the risk of convulsion due to cerebral oxygen toxicity is reported to be of the order of 1:10,000, but this risk may be considerably greater where patients have intracerebral pathology, or are subject to added risk factors such as pyrexia, hypoglycaemia, elevated inspired carbon dioxide levels, or increased cardiorespiratory workloads. There are rare anecdotal reports from North America of

oxygen convulsions in attendants breathing oxygen partial pressures of only 2 ATA. The possibility of unpredictable oxygen convulsions, not only in patients, but also in attendants, should be anticipated and individual therapeutic facilities should develop and document procedures for responding to such events and their foreseeable sequelae.

Pulmonary oxygen toxicity in staff is unlikely outside the context of saturation recompression of a diving casualty, but it may become a problem in patients who are either diving accident victims given frequent repeated treatments, or acutely ill patients in a hospital Intensive Care Unit (ICU) context who are receiving high levels of inspired oxygen between treatments. This possibility should be born in mind by medical staff when deciding the risks and benefits of alternate treatment regimens for individual patients. Calculation of Units of Pulmonary Toxicity Dose (UPTD) may help in some cases, but each case must be judged on its merits.

4.6.8 Thermal stress

For the comfort and safety of in-chamber attendants and patients, the Standard Operating Procedures for the therapeutic hyperbaric facility should specify ways in which the chamber environment can be maintained in thermal balance to avoid detrimental effects of excessive heat or cold to the chamber occupants. Upper and lower limits should be set and adhered to.

4.6.9 Fire safety

The risk of fire is a major and very real concern in the hyperbaric environment. The potential for accidental ignition of flammable materials is increased in the hyperbaric environment and their burning rate is markedly enhanced by a raised percentage of oxygen. Care must be taken to exclude various flammable substances and equipment that could be sources of ignition from hyperbaric chambers. For multiplace chambers, recommended fire prevention, detection, extinguishing systems and escape procedures are detailed in the British Hyperbaric Association publication, *Guide to Fire Safety Standards for Hyperbaric Treatment Centres* (see Annex C). Much of the information in this publication may be applicable to some monoplace chambers that are pressurised with air, however an individual risk assessment should be made in all cases. Chambers should have a written emergency policy detailing procedures for in-chamber fire prevention, and general actions in the event of fire in the chamber and/or facility buildings. Fire in the facility buildings and evacuation procedures including removing patients from the chamber should be specifically considered.

4.6.10 Electrical safety

Electrical safety and the risk of fire in the hyperbaric environment are inextricably linked. Guidance on electrical safety issues are detailed in the British Hyperbaric Association publication, *Guide to Electrical Safety for Hyperbaric Treatment Centres* (See Annex C).

4.6.11 Manual handling

Hyperbaric chambers treating unconscious, ventilated patients, and patients who are less than fully ambulant, particularly in multiplace chambers with no walk-in door, may recognise an appreciable risk of musculoskeletal injury to staff involved in the transfer of patients in and out of the chamber. Mechanical hoists, slide systems, and other patient handling aids should be used to control and reduce the risks to staff. The specific methods employed should be dictated by risk assessment in the particular context of

individual therapeutic units. Written procedures for reasonably predictable scenarios should be developed.

4.7 Hyperbaric Facility Systems Procedures

Standard Operating Procedures for technical and administrative aspects of Therapeutic Hyperbaric Facilities should be comprehensive and the following topics should be considered. The list is not exhaustive but may provide a helpful template. It includes both Health and Safety and clinical items:

- a. System and criteria for accepting patients referred for treatment.
- b. Call-out procedure for Hyperbaric Treatment Team and other staff.
- c. System Preparation - the following checklist headings are a guide to topics that should be covered:
 - i) Inspect working area to ensure it is free from hazards.
 - ii) Internal chamber.
 - iii) External chamber.
 - iv) Search and remove prohibited materials
 - v) Gas supply line-up and quantity for chamber.
 - vi) Gas supply line-up and quantity for built in breathing system.
 - vii) Reserve gas supply, line-up and quantity.
 - viii) Test environment conditioning system.
 - ix) Internal and external lighting function tests.
 - x) Fire suppression system line-up.
 - xi) Communications and emergency alert system function test.
 - xii) Patient support systems function test.
 - xiii) Brief medical and technical staff.
- d. Post hyperbaric operations:
 - a. Debrief staff.
 - b. Shut-down procedures and documentation, including "bends watch" procedure.

4.8 Patient Reception, Treatment and Disposition

Standard Operating Procedures for Therapeutic Hyperbaric Facilities should document guidelines or facility policy for the reception, treatment and discharge of patients in the facility. In general, reception of a patient should involve medical staff taking a clinical history or hand over of the patient's clinical details as his/her clinical condition indicates or allows. This should be accompanied by an appropriate pre-treatment assessment. The following is a guide of topics that can be developed for the following phases of patient management and associated issues:

- a. Method(s) of patient referral.
- b. Assessment of patient suitability for Category of chamber.
- c. Transport of patients to the therapeutic hyperbaric facility.
- d. Pre-treatment clinical assessment of patient for suitability of medical condition for hyperbaric oxygen treatment.
- e. Pre-treatment clinical assessment for other medical conditions which might be affected by hyperbaric treatment.
- f. Introduction of patient to the facility, including prohibited items, patient clothing policy, method of oxygen delivery.
- g. Patient briefed as to possible adverse effects of HBO.
- h. Informed consent to treatment.
- i. Patient-orientated procedures during compression.
- j. Maintenance of chamber environment at pressure.
- k. In-chamber patient management including physiological and clinical monitoring.
- l. Patient clinical record keeping;
- m. Patient-orientated procedures during decompression.
- n. Re-assessment of patient.
- o. Admission/transfer/referral for in-patient hospital care.
- p. Referral to other hyperbaric facilities.
- q. Patient discharged and review arrangements.
- r. Written instructions for the patient on discharge;
- s. Arrangements for transfer of clinical responsibility to alternative speciality when hyperbaric phase of treatment is complete;
- t. Written discharge summary;

4.9 Transfer Under Pressure

Transfer Under Pressure has been shown in over 20 years' experience in the UK to be rarely necessary. However where a facility exists for such a transfer, procedures for the transfer out (Categories 2-4) and reception of (Category 1) critically ill patients under pressure should be documented.

4.10 Equipment

Each Hyperbaric Therapy Provider shall ensure that suitable and sufficient plant and equipment is available whenever needed to carry out safely and without risk to health both the hyperbaric treatment and any action which may be necessary in the event of a reasonably foreseeable emergency connected with the hyperbaric treatment. New, or innovative, equipment, particularly medical equipment involved in patient care, will need to be considered carefully for its suitability and safety in a hyperbaric environment.

4.10.1 Face masks, hoods, or mechanical ventilators

The ability of face masks, hoods, or mechanical ventilators to reliably deliver 100% oxygen to patients during hyperbaric treatments needs to be assessed. Methods for cleaning and effective sterilisation of such equipment if it to be used by more than one

patient or attendant need to be specified.

4.10.2 Gases

Gases used in a hyperbaric facility need to be supplied, stored where necessary, and administered to patients (and staff) with due regard to the safety issues inherent in using pressurised gas and with recognition of the purity of gas composition required.

4.10.3 Storage cylinders

Standard Operating Procedures will need to specify that cylinders need to be appropriately stored in a designated area with consideration of the risk of fire or explosion in the storage area and to surrounding rooms or buildings. Cylinders in use should be adequately protected from causing physical damage due to falling. The risks of moving and handling cylinders should be assessed and controlled.

Gas cylinders will need to meet current legislative standards for suitability of design, fitness for purpose and safety of use. Prior to use, each cylinder needs have appropriate certification issued by a 'competent person' to verify the accuracy of markings, labelling and gas mixture.

4.10.4 Breathing gas supply

The correct use of breathing gases for hyperbaric chamber occupants is important to achieve the desired therapeutic effects for patients, to reduce the risk of cerebral oxygen toxicity, and to reduce the risk of DCI. Appropriate equipment will be needed to supply every chamber occupant with breathing gas of the correct composition and flow for all foreseeable situations. Sufficient quantities of breathing gas will be needed to deal with emergency situations.

4.10.5 Oxygen

Pressurised oxygen can fuel a serious fire or cause an explosion; it must therefore be stored and handled correctly. Any gas mixture containing more than 25% oxygen by volume will need to be handled as if it were pure oxygen.

4.10.6 Communications

Attendants inside the chamber while pressurised require a communication system that enables direct voice contact with the Supervising Chamber Operator on the surface and vice versa.

4.10.7 Equipment to carry and lift patients

All equipment used to carry or lift patients should be of appropriate design and fit for purpose. It should be maintained and checked at appropriate intervals to minimise the risk of failure during use.

4.11 Maintenance Procedures

Each Hyperbaric Therapy Provider shall ensure that the facilities, plant and equipment (including back-up equipment) is serviceable maintained in a safe working condition. SOPs should include details of routine maintenance and testing schedules for plant, machinery and medical equipment, and should comply with the Provision and Use of Work Equipment Regulations 1992.

4.11.1 Periodic examination, testing and certification

Detailed guidance on the frequency and extent of examination and testing required of all items of equipment used for hyperbaric chamber operation, together with the levels of competence required of those carrying out the work should be provided by the equipment supplier. Where appropriate, equipment and plant supplied for use in a hyperbaric chamber will need to comply with International, European and National standards (see Annex C).

4.11.2 Planned maintenance system

The Hyperbaric Therapy Provider will need to establish a system of planned maintenance for plant and equipment to demonstrate compliance with the relevant regulations. Such a system may be based on either passage of time or amount of use, but ideally will be based on a combination of both.

4.11.3 Equipment register

An equipment register will need to be maintained by the Hyperbaric Therapy Provider, with copies of all relevant certificates of examination and test.

4.11.4 Written scheme of examination

The Pressure Systems and Transportable Gas Containers Regulations 1989 apply to plant that contain compressed air or other gasses at a pressure greater than 0.5 bar (about 7 psi) above atmospheric pressure. This means that decompression chambers will need to conform with the requirements. The Regulations require users to establish the safe operating limits of the plant. A suitable written scheme has to be drawn up or certified by a competent person for the examination at appropriate intervals of most pressure vessels and all safety devices, and any pipework.

5. EMERGENCY PROCEDURES

Action plans detailing procedures to be followed in the event of both medical and system emergencies should be documented as part of the facility SOPs.

5.1 Medical Emergencies

Medical emergencies that require technical action as well as medical input for their prompt and appropriate management are inherent and predictable occurrences during therapeutic hyperbaric facility operations involving patients. The lack of immediate access to the patient by specialist support staff, and the technical constraints of the hyperbaric environment complicate the management of these medical emergencies. Different therapeutic hyperbaric facilities may approach such emergencies in different ways, depending on their specific circumstances. However, each facility should develop and document procedures to guide the actions of staff in the event of such emergencies. Emergency Procedures must be clearly defined, understood and exercised. Areas that warrant attention include:

- a. cardiorespiratory arrest and procedures for safe defibrillation;
- b. convulsions (including oxygen convulsions);
- c. loss of consciousness;

- d. pneumothorax diagnosed under pressure;
- e. vomiting;
- f. pressure-related injuries;
- g. pulmonary oxygen toxicity; and
- h. decompression illness in patients or staff.

5.2 System Emergencies

While every effort may be made to prevent the occurrence of system failures, technical and physical emergencies may occur and procedures should be in place to deal with them. Different therapeutic hyperbaric facilities may approach such emergencies in different ways, depending on their specific circumstances. However, as with medical emergencies, each facility should develop and document clearly defined procedures to guide the actions of staff. Facility personnel required to respond in these emergency procedures must be trained in their roles, and be competent to undertake them. Emergency procedures should be periodically exercised. Areas that warrant attention include:

- a. uncontrolled change of pressure;
- b. loss of gas supply;
- c. contaminated atmosphere;
- d. high oxygen levels in chamber atmosphere;
- e. overheated chamber;
- f. fire in chamber;
- g. fire in building;
- h. loss of communications;
- i. power failure; and
- j. bomb threat.

ANNEX A

DOCUMENTATION AND RECORD KEEPING

Therapeutic hyperbaric facilities should record and maintain data related to both the Health and Safety, technical and clinical aspects of their operation.

Health and Safety Records

Data related to risk assessments of identified hazards and control measures or procedures should be recorded and all staff potentially affected by such hazards should be made aware of this information, which should be an intrinsic part of the facility's Standard Operating Procedures documentation. A copy of SOPs should be kept adjacent to the chamber during operation and be readily accessible to the Supervising Chamber Operator and all staff.

Non-Clinical and Technical Records

The non-clinical and technical records that should be documented include:

- a. Name and address of the Hyperbaric Therapy Provider.
- b. Date to which entry relates and name of Supervising Chamber Operator (an entry must be completed daily by each Supervising Chamber Operator for each hyperbaric treatment).
- c. Location of the hyperbaric treatment facility.
- d. Names of all those in the hyperbaric treatment team and their role.
- e. Patient(s) names.
- f. Breathing apparatus and breathing mixture used by each patient and attendant during the hyperbaric treatment.
- g. The Hyperbaric Treatment protocol followed (which may be a reference to a standard schedule in the Standard Operating Procedures). Any deviation from a standard schedule should include details of the pressures and the duration of time spent by chamber occupants at those pressures (or depths) during decompression.
- h. Time at which each patient or attendant leaves atmospheric pressure and returns to atmospheric pressure plus his/her bottom time.
- i. Any emergency or incident of special note which occurred during the hyperbaric treatment, including details of any reported change in clinical condition of the patient, locking in or out of equipment, and any treatment given.

- j. Any defect recorded in the functioning of any plant or equipment used in the hyperbaric treatment.
- k. Particulars of any relevant environmental factors during the operation.
- l. Any other factors likely to affect the safety or health of any persons engaged in the operation.

Clinical Records

It is essential that comprehensive and accurate clinical records are kept of every aspect of hyperbaric treatments. These records are of value for the current and any subsequent treatments of the patient and may be critical if litigation ensues. There may be value in making an electronic recording of communications between those in the chamber and attendants outside. Medical records are the property of the Hyperbaric Therapy Provider, who may also be the Medical Director and/or the Hyperbaric Duty Doctor and normal conventions of medical confidentiality will apply. As a general rule in civil law the Statutes of Limitation preclude litigation being initiated more than three years after treatment of an adult but most institutions feel it prudent to retain records for a longer period. NHS Circulars give comprehensive advice on the retention of clinical and other records and it is recommended that non-NHS hyperbaric facilities adopt similar procedures.

Clinical records relating to a specific patient which should be made and considered for retention might include:

- a. Medical and nursing records (signed, timed and dated), including admission procedures and assessment, investigations e.g. X-rays, care plans, record of care given, response to treatment including significant changes, discharge/transfer procedures, consent for treatment where necessary, medical letters and discharge summaries; and
- b. Records of hyperbaric therapy profiles.

Other documentation, which should be held by the hyperbaric facility, might include:

- a. protocols or the assessment and treatment of all conditions for which the facility offers hyperbaric therapy;
- b. staff personnel records, e.g. training record, qualifications, competence, appointment;
- c. staff duty rotas;
- d. staff hyperbaric exposure records;
- e. equipment and maintenance records, e.g. equipment register, statements of fitness for purpose, test certificates when appropriate, e.g. gauges, pressure vessels, pressure hoses, planned maintenance schedule, defect reporting log, with a record of defects/faults;

- f. chamber-checks and air/gas purity tests conducted;
- g. stock and issue list for medical stores;
- h. pharmacy stock and issue list where appropriate;
- i. written standards for quality of service, including any audit assessments; a purpose-designed information sheet for patients and others regarding hyperbaric therapy;
- k. a patient questionnaire as a quality measuring tool; and
- l. reference materials and journals as well as policy documents issued by professional bodies.

ANNEX B

DETAILS TO BE INCLUDED IN THE PERSONAL HYPERBARIC EXPOSURE LOG OF MEDICAL ATTENDANTS OR TECHNICAL ATTENDANTS TO HYPERBARIC TREATMENTS

1. Name and address of the Hyperbaric Therapy Provider.
2. Date to which entry relates and name of Supervising Chamber Operator.
3. Location of the therapeutic hyperbaric facility.
4. The maximum depth reached on each occasion (and standard treatment schedule).
5. The time of leaving atmospheric pressure, the duration at treatment depth, and the time of return to atmospheric pressure.
6. Breathing apparatus and breathing mixture used.
7. Any decompression illness, discomfort or injury suffered.
8. Any emergency or incident of special note which occurred during the hyperbaric treatment.
9. Any other factor relevant to the staff member's health or safety.
10. Signature of the staff member and the Supervising Chamber Operator.

ANNEX C

APPLICABLE LEGISLATION

The following list of legislation is likely to be relevant and/or applicable to therapeutic hyperbaric treatment facility activities. Statutory Instrument (SI) numbers and Guidance or Approved Code of Practice reference numbers are supplied in some cases. The list is not intended to be comprehensive or exhaustive:

The Health and Safety at Work etc Act 1974 (Guidance L1).

The general enabling legislation under which much of the following more specific regulations fall.

The Management of Health and Safety at Work Regulations 1999 (MHSAW) (SI 3242) These regulations overlap with many existing health and safety regulations. Their requirements include the need for risk assessment, health and safety arrangements, and health surveillance and for employers to have access to competent help in applying the provision of health and safety law. There are also requirements for training staff and for co-operation and co-ordination where two or more employers or self-employed persons share a workplace.

These regulations require employers to take particular account of the risks to new and expectant mothers when assessing risks at work. Pregnant workers should not work in hyperbaric chambers and employers should therefore offer suitable alternative work to them. If this is not possible, the employer will need to give the worker paid leave for as long as necessary to protect her health or safety or that of her child. Employers should make it clear that employees need to inform them as early as possible in the event of pregnancy.

Confined Spaces Regulations 1997 (Guidance L101) Any assessment under the Management of Health and Safety at Work Regulations of work in a hyperbaric chamber, is likely to identify risks of serious injury arising from work in the confined space of the chamber. Consequently the Confined Spaces Regulations 1997 will apply to this work. A key duty under these regulations includes avoiding entry into the confined space, but clearly this is rarely appropriate in the context of patient care in a therapeutic hyperbaric facility. However, other key duties under these regulations are:

- if entry into the confined space is unavoidable, following a safe system of work;
- putting in place adequate emergency arrangements before the work starts.

These elements are plainly applicable to therapeutic hyperbaric facility operations. The hyperbaric therapy provider will therefore need to ensure a safe system of work and adequate emergency arrangements for their own employees and others working in the chamber. Essential elements of a system of work for a chamber include appointing a supervisor to check safety at each stage, ensuring

that staff are competent and suitable for the work and preventing anyone taking tools or equipment into the chamber that may cause a fire.

Control of Substances Hazardous to Health (COSHH) Regulations 1999 apply to the exposure of employees and others to hazardous substances (including hazardous micro-organisms) in therapeutic hyperbaric chambers, but do not apply where the substance is hazardous *solely* because it is at high pressure. Working in an increased pressure may increase the toxic response to a substance. Consequently specialist advice may be necessary to interpret the application of the occupational exposure limits set under the COSHH Regulations with particular regard to short term exposure limits, where appropriate.

Chemicals (Hazard Information and Packaging and Supply) Regulations 1994 require suppliers to classify, label and package dangerous chemicals and provide safety data sheets for them.

Provision and Use of Work Equipment Regulations 1992 (SI 2932, Guidance Note L22) require that equipment provided for use at work including machinery is safe.

Manual Handling Operations Regulations 1992 (SI 2793, Guidance L23) cover the moving of objects by hand or bodily force.

Personal Protective Equipment Regulations 1992 (SI 2966) Amended 1994, (SI 2326) require employers to provide appropriate protective clothing and equipment for their employees.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) (SI 3163) (Guidance L73). The current Regulations are designed to provide a national record of certain types of injury, diseases and dangerous occurrences that might jeopardise the health and safety of workers. There is a requirement in RIDDOR for employers to report decompression illness, dysbaric osteonecrosis, serious barotrauma resulting in lung damage or arterial gas embolism, or minor ear or sinus barotrauma and its sequelae where the employee is prevented from working normally for 3 or more days. There is also a requirement to report certain explosions and fires and the failure of a vessel under pressure, where that failure has the potential to cause the death of any person.

Pressure Systems and Transportable Gas Containers Regulations 1989, (SI 2169) (Guidance HS(R)30). Pressure vessels require a written scheme of examination.

The Simple Pressure Vessel, Safety Regulations 1991, (SI 2749) Amended 1994, (SI 3098)

The Diving at Work Regulations 1998, (SI 2776)

Carriage of Dangerous Goods, Classification, Packaging and Labelling and Use of Transportable Pressure Vessels Regulations 1996, (SI 2092).

Fire Precautions, Work Place Regulations 1997, (SI 1840)

Noise at Work Regulations 1989 (SI 1790) require employers to take action to protect employees from hearing damage.

Electricity at Work Regulations 1989 (SI 635) Guidance HS(G)25 require people in control of electrical systems to ensure they are safe to use and maintained in a safe condition.

Electrical Equipment Safety Regulations 1994, (SI 3260)

Construction (Design and Management) Regulations 1994 cover safe systems of work on construction sites.

Health and Safety, (Display Screen Equipment) Regulations 1992 (SI 2792) set out requirements for work with visual display units.

The Health and Safety, Safety Signs and Signals Regulations 1996, (SI 341)

Health and Safety (First Aid) Regulations 1981 (ACOP 42) cover requirements for first aid.

Workplace (Health, Safety and Welfare) Regulations 1992 cover a wide range of issues such as ventilation, heating, lighting, seating and welfare facilities.

The Health and Safety Information for Employees Regulations 1989 (SI 682) Amended 1995, (SI 2923) require employers to display a poster telling employees what they need to know about health and safety.

Health and Safety (Consultation with Employees) Regulations 1996 (SI 1513) Employers have a duty to consult employees on health and safety matters. The Safety Representatives and Safety Committees Regulations 1977, as amended, require employers to consult safety representatives appointed by any trade unions they recognise. Under the Health and Safety (Consultation with Employees) Regulations 1996, employers must consult any employees not covered by the 1977 Regulations.

The Safety Representatives and Safety Committees Regulations 1977

Employers' Liability (Compulsory Insurance) Regulations 1969 require employers to take out insurance to cover their liability for accidents and ill-health sustained by their employees.

Employers Liability Regulations 1973 Amended 1994, (SI 3301)

The Health and Safety (Training for Employment) Regulations 1990 set out how certain people being trained for employment should be treated for the purposes of health and safety law.

Disability and Discrimination Act 1995

Health and Safety, Miscellaneous Provisions Regulations 1992, (SI 1811).

Health and Safety, Enforcing Authority Regulations 1989, (SI 1903).

OTHER APPLICABLE CODES OF PRACTICE AND GUIDANCE

COP 37 - Safety of Pressure Systems, Approved Code of Practice

COP 42 - First Aid at Work, Approved Code of Practice

HS[R]25 Memorandum of Guidance on Electricity at Work Regulations 1989

HS[G]39 - Compressed Air Safety

GS4 - Safety in Pressure Testing

HS Bulletin - Pressure Systems: Examination Scheme 1993

EH40/97 - Occupational Exposure Limits 1997

INDUSTRY GUIDANCE AND CODES OF PRACTICE

Faculty of Occupational Medicine Report - A code of Good Working Practice for the Operation of Hyperbaric Chambers for Therapeutic Purposes.

British Hyperbaric Association - Guide to Electrical Safety Standards for Hyperbaric Treatment Centres

British Hyperbaric Association - Guide to Fire Safety Standards for Hyperbaric Treatment Centres

Association of Offshore Diving Contractors [AODC] Guidance Notes, for example:

- 010 Testing, Examination and Certification of Gas Cylinders
- 014 Minimum Quantities of Gas Required Off-Shore
- 028 Divers' gas supply
- 029 Oxygen Cleaning
- 030 Acrylic Plastic View Ports
- 035 Code of Practice for the Safe Use of Electricity Under Water
- 041 The Initial and Periodic Testing, Examination and Certification of Diving Plant and Equipment
- 053 Offshore Diving Supervisor and Life Support Technician Schemes.
Examination of Compressed Air Systems

- 056 Code of Practice on the initial and periodic examination, testing and certification of diving plant and equipment
- 062 Use of battery operated equipment in hyperbaric conditions
- ADC 95 Minimum criteria to be met by a surface supply inland /inshore air diving panel for hyperbaric treatments in the UK.

Diving Safety Memoranda (DSM), for example:

- DSM 211990 - Exposure limits for air hyperbaric treatments.
- DSM 1011983 - Divers' air gas supply systems.

Diving Medical Advisory Committee [DMAC] Guidance Notes, for example:

- 07 Flying After Diving
- 09 Fitness to Dive After Neurological DCI
- 13 Fitness to Return to Diving
- 16 Saturation Chamber Hygiene
- 17 Training of Doctors involved in the Treatment and Examination of Professional Divers
- 27/28 Provision of Emergency Medical Care of Divers in Saturation

Department of Energy Code of Practice for the Safe Use of Electricity Under Water

Institution of Electrical Engineers [IEE] Wiring Regulations

British Compressed Air Society [BCAS] - Guide to the Selection and Installation of Compressed Air Services

British Compressed Gases Association - Code of practice 23: Application of 'Pressure systems and transportable gas containers regulations 1989' to industrial and medical pressure systems installed at consumer premises (1123 A2).

Chartered Institution of Building Services Engineers (CIBSE).
Lighting guides (LG 2) Hospitals and health care buildings (599 G27).

UK Offshore Operators Association [UKOOA] Publications, for example:

- Rig Medic Training
- Emergency Medical Equipment Offshore

MOD PUBLICATIONS

BR 2806 MoD Royal Navy Diving Manual

BR 2807 Breathing Gas, Charging and Storage Arrangements

BR 3013/Vol1&2 Admiralty Pipework Standards

Naval Engineering Standards [NES] e.g.

NES 314 - Compressed air Systems

NES 315 - Air Compressors

NES 317 - Air Storage Reservoirs [Steel]

NES 372 - Oxygen Cleaning

NES 373 - Compressed Air System Cleanliness

DGUW[N] Pub 84155 - Mine Counter Measures and Diving, MCMD Division,
Recommended Oxygen Cleaning Procedure

Defence Standards - Def. Stan. e.g.

Def. Stan. 68-75/3, Diving Gas Quality

NATIONAL STANDARDS DOCUMENTS

British Standard 6869, 1997 - Code of Practice for Procedures for Ensuring the Cleanliness of Industrial Process Measurement and Control Equipment in Oxygen Service.

British Standard 4275, 1974 - Recommendations for the Selection, Use and Maintenance of Respiratory Protective Equipment.

British Standard 341 - Valve Fittings for Compressed Gas Cylinders.

British Standard 1319 - Specification for Medical gas Cylinders, Valves and Yoke Connections.

British Standard 5430 - Specification for Periodic Inspection and Testing and Maintenance of Transportable Gas Containers

British Standard EN 250, 1993 - Respiratory Equipment, Open Circuit Self Contained Compressed Air Diving Apparatus. Requirements, Testing, Marking.

British Standard EN 1089-3, 1997 Transportable Gas Cylinders - Cylinder Identification Part 3. Colour Coding.

British Standard 4001 Part 2, 1995, Standard Diving Equipment [Diving Air Quality]

British Standard 5500. 1997, Specification for Unfired Pressure Vessels.

British Standard 2881, Specification for cupboards for the storage of medicines in health care premises. (995 C1)

British Standard 4533 Sect 102.55 Specification for luminaires for hospitals and health care buildings. (794 L25)

British Standard 5724 Medical electrical equipment Pt 2: Particular requirements for safety.

British Standard 5724 Sect 2.27 Specification for oxygen analysers for monitoring patient breathing mixtures. (669 L14)

Compressed Gas Association Inc. CGA G-4.1, 1996 - Cleaning Equipment for Oxygen Service.

American Society of Mechanical Engineers [ASME] VIII, Pressure Vessel Manufacture

ASME VIII, Pressure Vessels for Human Occupancy [PVHO]

INTERNATIONAL CLASSIFICATION SOCIETY RULES

Lloyds Register of Shipping - Rules and Regulations for the Construction and Classification of Submersibles and Diving Systems

Det Norske Veritas - Rules for the Construction and Classification of Diving Systems

Germanischer Lloyd - Rules for Underwater Technology - Diving Systems and Diving Simulators

American Bureau of Shipping, Rules for Building and Classing Underwater Systems and Vehicles

HEALTH CARE CODES OF PRACTICE AND GUIDANCE

British Medical Association Codes of practice:

Safe use and disposal of sharps (1461 A2)

Sterilisation of instruments and control of cross infection. (1626 H1)

Department of Health Publications:

Health circulars:

HC 82/16 Health services management - supply of information about hospital patients in context of civil legal proceedings (2083 E23).

HC 84/4 Health services management - vaccination and immunisation policy for NHS staff (2082 B7).

Health Memoranda:

HM 59/6 National health service - control of staphylococcal infections in hospitals (2084 D15).

Health Technical Memoranda:

HTM 1 Anti-static precautions - rubber, plastics and fabrics. (Produced with WOF 493 A2)

HTM 22 Piped medical gases, medical compressed air and medical vacuum installations. (DHSS & Welsh Office. 493 H14).

HTM 83 Fire safety in health care premises - general fire precautions. 230 G4.

Local authority circulars:

Monograph: Control of substances hazardous to health - guidance for the initial assessment in hospitals. (663 B8)

Monograph: Safety at work, health service catering. (2050 D1).

Health and Safety Authority Publications:

Guidance notes: Violence at work in health services sector (8105 F14).

Monograph: Occupational safety and health training - report of the Advisory Committee (8087 J13).

Report of advisory committee on Health Services Sector to Health and Safety Authority - including guidelines on occupational health and safety training (8087 E7).

Who cares for carers? (8126 L13).

Health and Safety Executive:

Health Services Advisory Committee
Occupational health services in the health service (308 130).

Department of Environment, Transport and Regions:

UG 25 Upgrading Guidance - Secretary of State's guidance:
Clinical wastes (317 J11).

OTHER SOURCES OF INFORMATION AND GUIDANCE

Undersea and Hyperbaric Medical Society [UHMS], e.g. Mono-Place Hyperbaric Chamber Safety Guidelines 1991

National Fire Prevention Association [NFPA], 1999 Guide, Chapter 19, Hyperbaric Facilities

British Occupational Hygiene Society, Technical Guides e.g. No. 6 - Sampling and Analysis of Compressed Air To Be Used For Breathing Purposes.

Undersea and Hyperbaric Medical Society [UHMS], Hyperbaric Oxygen Therapy: A Committee Report (Revised 1996)..

European Committee for Hyperbaric Medicine: 1st European Consensus Conference on Hyperbaric Medicine: Reports and Recommendations, Lille, 1994