National Board of Diving & Hyperbaric Medical Technology

# Hyperbaric Facility Accreditation Manual



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#### INTRODUCTION

The National Board of Diving & Hyperbaric Medical Technology (National Board) is pleased to announce the introduction of a hyperbaric facility accreditation program.

With over four decades of hyperbaric operations and safety leadership and a cadre of highly regarded subject matter expert surveyors, the National Board is uniquely positioned to execute this important undertaking.

Displaying the National Board's accreditation seal is verification that a hyperbaric facility has been formally evaluated, that its operations and safety policies and procedures documentation is deemed compliant, and most critically, being applied consistent with prevailing regulations, codes, standards and authoritative guidelines.

Beta site testing of multiplace and monoplace hyperbaric delivery system programs is nearing completion, and the National Board is now accepting accreditation applications. To schedule a survey or seek additional information please complete the form below.

### BACKGROUND

Hyperbaric medicine enjoys almost two centuries of practice. First proposed in 1664, functional multi-occupancy chambers were introduced in the 1830's. Air was both the chamber compression and occupant breathing medium. Proposed uses were entirely speculative and unlikely to have resulted in meaningful clinical gain. During the latter 19<sup>th</sup> century, however, and based on sound mechanistic rationale, hyperbaric chambers were employed as primary therapy for mass transit tunneling and bridge caisson compressed air activities that resulted in decompression sickness and the chamber continues to represent primary therapy.

Oxygen eventually replaced air as the breathing/treatment medium. This led to the identification of additional therapeutic mechanisms associated with hyperbaric hyperoxic exposure and a broadened list of uses. Design and operational characteristics of the multi-occupancy chamber have remained largely unaltered over the ensuing years, such that it is arguably the oldest medical technology in unchanged state today. A single occupancy chamber was introduced in the 1950s and has evolved as the most common hyperbaric delivery system in the United States.

Hyperbaric chambers support naval and military aviation operations, professional, commercial, scientific and recreational diving activities and are found in specialized research settings. They have been increasingly incorporated into mainstream medical practice, both in hospitals and within hospital-affiliated free-standing clinics. There are also examples of independently operated hyperbaric programs. In each of these settings, the chamber's design, construction, installation and operation are each expected to comply with prevailing regulations, codes, standards, authoritative organizational oversight and best practices. Compliance is not uniform, however, and deficiencies are not always evident or ignored. This has the effect of increasing risk of adverse events in patients and those in proximity to the hyperbaric delivery system. The introduction of hyperbaric chambers, some soft-sided with low operating pressures, not designed to authoritative standards, further increases the risk profile. Manufacturers of these chambers rely on deceptive marketing practices to attract customers who introduce them into

unregulated clinics, private offices, spas, fitness centers, offices and even private homes for personal use. Proposed uses of these chamber types are long, likewise promoted on deceptive marketing behaviors, invariably lacking credible scientific support or even sound mechanistic rationale.

The practice of hyperbaric medicine is considered a mastered medical technology only when undertaken by appropriately trained health care professionals employed in regulated health care settings, using compliant chambers. Complications and side effects are uncommon and most resolve without sequalae. There are exceptions, none more potentially devastating than a chamber fire.

The National Board believes that determination of a hyperbaric medicine program's operations, safety and compliance is best assessed through independent authoritative third-party analysis. The National Board is such an authority and offers a hyperbaric facility accreditation program. Operational, safety and compliance metrics are assessed by subject matter experts during onsite surveys that focus on tracer-like activities, and a detailed remote review of program documentation.

## ACCREDITATION SURVEY PROCESS

#### On-site

Undertaken by surveyors with expertise related to host program hyperbaric delivery system type. Surveyor team members will be identified at least 30 days prior to their arrival.

The host program is expected to maintain normal patient care and operational activities during the survey.

One team member, preferably the program manager/director if they are fully conversant with the technical scope of the survey, is expected to be available throughout the visit.

- · Inspection of the hyperbaric facility/environment of care and supportive infrastructure.
- · Confirm presence of chamber and ancillary equipment operations manuals.
- Review of hyperbaric facility staffing patterns, personnel qualifications, certification levels, skills/knowledge maintenance and periodic updating.
- Evaluation of employee orientation skills checklist(s).
- · Observe hyperbaric facility startup and end of day procedures and related documentation.
- Observe hyperbaric treatments, pre-treatment facility and patient checks, safety "time outs", post-treatment facility and patient checks, and related documentation.
- Observe multiplace chamber inside attendant pre-and post-treatment screening.
- $\cdot$   $\;$  Observe multiplace chamber inside attendant decompression procedure.
- · Observe infection control practices.
- · Review of prohibited items; "Go/"No Go" checklist. Observe safety "timeout".
- Review Prohibited Item Authorization Form, and any such use.

- Examine patient supplied clothing and chamber linens.
- · Team members questioned regarding select emergency procedures.
- Observe informed consent process, should new patients be present.
- · Observe rendering hyperbaric provider attendance and supervision.
- Determine educational texts available to facility personnel.

#### Off-site

Off-site review undertaken via email document transfer to <a href="www.nbdhmt.org/fileupload">www.nbdhmt.org/fileupload</a>

To complete the off-site review of the Facility Accreditation the following documentation must be received a **minimum of 60 days prior** to the survey start date. All information and documentation related to the accreditation survey is considered confidential by the NBDHMT. Its use will be strictly limited to the accreditation process and not otherwise disclosed unless required by law.

File formats accepted are word, excel, and PDF. Please name each file by the Item number and facility name. Note this name in the top left corner of each page. Example: Item1NBDHMT.pdf

If you prefer to combine the documentation upload, you may do so in a PDF format with each page notating the item number in the top left corner as described above. Please gather the full list of items prior to submission. Offsite Survey documents will not be accepted piecemeal.

- Policy and Procedure Manual and Treatment Tables.
- · Sample redacted consultation and patient informed consent.
- · Hyperbaric facility emergency procedures.
- · Inside attendant health screening policy (multiplace chamber programs).
- · Medical Staff Office Hyperbaric Physician Credentialing Policy (hospital affiliated facilities).
- · New employee orientation, staff competencies and provider/staff continuing education logs.
- · Quality Assurance Performance Improvement plan.
- · Infection control policy.
- · Sample monthly/periodic safety drills, topics and attendance log documentation.
- · Most recent hyperbaric chamber evacuation drill documentation.
- Recent monthly staff meeting topics and attendance log documentation.
- · Sample monthly/periodic chamber maintenance logs.
- · Chamber manufacture's service history records, last visit.
- · Compressed gas cylinder transfer, handling, storage and use policy.
- · Nursing assessment policy and sample redacted nursing assessment.

# CONFIDENTIALITY OF SURVEY PROCESS

All information and documentation related to the accreditation survey is considered confidential by the National Board. Its use will be strictly limited to the accreditation process and not otherwise disclosed unless required by law.

# REFERENCED AUTHORITATIVE ORGANIZATIONS AND TEXTS

- · American Society of Mechanical Engineers Boiler and Pressure Vessel Code
- · American Society of Mechanical Engineers Pressure Vessel Human Occupancy 1
- · American Society of Mechanical Engineers Pressure Vessel Human Occupancy 2
- · American Society for Testing and Materials Safe Use of Oxygen and Oxygen Systems
- Baromedical Nurses Association Hyperbaric Oxygen Therapy Nursing Guidelines
- CMS Conditions for Coverage and Participation
- Compressed Gas Association Policy C-4
- · Det Norske Veritas (DNV) National Integrated Accreditation for Healthcare Organizations
- · National Board of Diving & Hyperbaric Medical Technology Position Statements
- National Institute of Standards and Technology; Compressed Gas Safety
- · Facility Specific Manufacturer's Hyperbaric Chamber Operations Manual
- National Fire Protection Association 55, 99 and 101 Current Editions
- · Risk Assessment Guide for Installation and Operation of Clinical Hyperbaric Facilities
- The Joint Commission (TJC)
- Undersea & Hyperbaric Medical Society; Hyperbaric Facility Design & Operations Guidelines

### ACCREDITATION SURVEY DECISIONS

The National Board's decision will be delivered within fifteen (15) working days of survey completion, as follows:

- Accreditation awarded.
- Accreditation pending resolution of minor deficiencies; no additional site visit anticipated.
- Accreditation pending resolution of significant deficiencies; additional "direct expenses only" site visit may be required.
- Accreditation denied, deficiencies provided. Any re-application must be no sooner than six months from this decision date.

## ACCREDITATION COMPLIANCE AND RENEWAL

The accreditation period is three (3) years. Renewal applications should be submitted no later than 90 days prior to expiration date to ensure no lapse in accreditation.

Maintenance of accreditation requires there be no change in institutional/business oversight, site location, scope of services, hyperbaric delivery system type, Program Director (or equivalent title), and Hyperbaric Safety Coordinator (or equivalent title). If there is intent to alter any above program aspects, the National Board must be notified 90 days in advance. An exception to this notice period is permitted should an unanticipated change in referenced personnel occur. This will require National Board notification at the earliest convenience. Depending upon the extent of any such change(s), the National Board reserves the right to require a follow-up on-site visit for maintenance of accreditation.

# ACCREDITATION SURVEY FEE SCHEDULE\*

Non-refundable application fee: \$1,000.00 \*\*

Survey fee: \$5,500.00, due 30 days prior to scheduled site visit<sup>†</sup>

Re-accreditation fee: \$5,000.00

\* All fees are quoted in USD and apply to North American facilities. International survey fees are quoted upon request.

<sup>\*\*</sup> Application fee will be invoiced after Accreditation Application has been approved.

<sup>&</sup>lt;sup>†</sup> If a facility elects to cancel a scheduled survey visit after the designated surveyors have formalized travel arrangements, the facility will be responsible for any non-refundable expenses. If a facility wishes to reschedule an already scheduled visit, the facility will be responsible for any surveyor change fees.



# National Board of Diving & Hyperbaric Medical Technology Hyperbaric Facility Accreditation Application

Accreditation survey requests are welcomed and considered on an individual basis. Upon receipt of a completed application the National Board will undertake a review to determine if that facility meets accreditation survey criteria. Applicants will be notified of the National Board's decision within five (5) business days. If the decision is to accept the application, a \$1,000.00 USD deposit is required to initiate the survey scheduling process. If the application is declined, the basis for this decision will be provided.

Information obtained from a completed application will allow the National Board to determine whether criteria to undertake an accreditation survey has been met, as well as survey team size and composition.

	•					
Facility Nam	ıe					
Address						
Website						
Primary Contact Name						
Title		(	Credentials			
Telephone		Email				
Program Det	ails	Year	r hyperbaric pr	ogram began		
			Chamber Type all that apply)	9		
☐ Multiplace	How many?	Manufacturer(s)		NB#		
☐ Duoplace	How many?	Manufacturer(s)		NB#		
☐ Monoplace	How many?	Manufacturer(s)		NB#		
	Oxygen Comp	oressed Monoplace	☐ Yes ☐ No			
Service Type						
24/7 Availabili	ity □ Yes □ No	Hospital Affiliated	☐ Yes ☐ No	Associated Wound Center	□ Yes □ No	
Treat Inpatie	nt □ Yes □ No	Hospital Based	☐ Yes ☐ No	Free-Standing Building	☐ Yes ☐ No	
		TT 1		Trailer or Vehicle Mounted	☐ Yes ☐ No	
			ric Personnel			
Number of <b>ful</b> l			Number of <b>pa</b>			
Number of attending/supervising hyperbaric <b>providers</b> MD/DO NP Other			her			
List primary specialties of <b>providers</b>						
Comments or Questions:						



# National Board of Diving & Hyperbaric Medical Technology Survey Documentation Checklist

To complete the off-site review of the Facility Accreditation the following documentation must be received a **minimum of 60 days prior** to the survey start date. All information and documentation related to the accreditation survey is considered confidential by the NBDHMT. Its use will be strictly limited to the accreditation process and not otherwise disclosed unless required by law.

File formats accepted are word, excel, and PDF. Please name each file by the Item number and facility name. Note this name in the top left corner of each page.

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Upload all documents securely at <a href="https://www.nbdhmt.org/fileupload">www.nbdhmt.org/fileupload</a>. <a href="https://www.nbdhmt.org/fileupload">Application must be approved prior to documentation uploading</a>.

Item	Description
1	Policy and Procedure Manual and Treatment Tables.
2	Sample redacted consultation and patient informed consent.
3	Hyperbaric facility emergency procedures.
4	Inside attendant health screening policy (multiplace chamber programs).
5	Medical Staff Office Hyperbaric Physician Credentialing Policy (hospital affiliated facilities).
6	New employee orientation, staff competencies and provider/staff continuing education logs.
7	Quality Assurance Performance Improvement plan.
8	Infection control policy.
9	Sample monthly/periodic safety drills, topics and attendance log documentation.
10	Most recent hyperbaric chamber evacuation drill documentation.
11	Recent monthly staff meeting topics and attendance log documentation.
12	Sample monthly/periodic chamber maintenance logs.
13	Chamber manufacture's service history records, last visit.
14	Compressed gas cylinder transfer, handling, storage and use policy.
15	Nursing assessment policy and sample redacted nursing assessment.