Inquiry: Under what conditions may portable nonmetallic braid-reinforced flexible membrane hyperbaric stretchers and/or treatment systems be used in construction under the rules of PVHO-1–2012?

Reply: It is the opinion of the Committee that portable nonmetallic braid-reinforced flexible hyperbaric stretchers and/or treatment systems may be constructed under the requirements of PVHO-1–2012 and be marked as a PVHO when the requirements of PVHO-1–2012 with the following exceptions and additions have been met.

NOTE: Case 12 was originally approved in 2009 under the rules of PVHO-1–2007. Revisions made to section 6 of this Case have allowed compliance with PVHO-1–2012.

1 GENERAL

This Case covers a range of similarly designed and constructed PVHOs. The PVHOs may be of different shapes and sizes and have different pressure ratings depending on their application. The parameters are limited to those listed below.

The flexible PVHOs shall each comprise a braided liquid crystal polymer (LCP) fiber tube [Fig. 12-1(b)] enclosing a pressure-retaining membrane of impermeable polyurethane-coated nylon [Fig. 12-1(c)]. The membrane is rigidly attached to a number of segmented aluminum clamp plates [Fig. 12-1(d)] at each end of the tube. The LCP fiber tube and coated nylon membrane are totally enclosed in a reinforced fire-retardant, polyurethane-coated nylon outer cover [Fig. 12-1(a)] to protect the tubes from normal wear and tear and ultraviolet exposure (sunlight), as well as for retaining the lifting straps in position.

The braided LCP tube also encloses two flexible LCP fiber rings [Fig. 12-1(f)], one at each end of the tube, outboard of the clamp plates. The flexible LCP fiber rings and clamped membrane are sufficiently flexible to allow for the patient to enter and exit the PVHO, as well as for insertion and removal of the end closures. The end closures comprise acrylic spherical sector windows [Fig. 12-1(g)] set in nylon protection rings [Fig. 12-1(e)] that are suitably shaped to engage with the pressure-retaining membrane. Services to the PVHO are provided through an aluminum penetrator plate, centrally positioned in one end closure. The other end may be fitted with a medical lock or an additional penetrator plate.

The PVHOs and associated systems shall be designed, constructed, inspected, tested, marked, and installed (if applicable) to PVHO-1–2012, Sections 1, 2, 3, 4, 5, and 6 (as applicable), with exceptions and additions detailed in this Case.

All PVHOs shall fall within one of the categories in Table 12-1 depending on their size, number of occupants, maximum allowable working pressure (MAWP), service, and gas outlets/built-in breathing system (BIBS).

The following design and performance criteria shall also apply:

(a) The MAWP shall not exceed 75 psig (0.52 MPa).
(b) The outside diameters of the PVHOs shall be between 23 in. and 48 in. (58.5 cm and 122 cm).
(c) The maximum length shall not exceed 120 in. (305 cm).
(d) The vessel shall have removable end closures, incorporating windows.
(e) The design number of pressure cycles shall not exceed 4,000 cycles.
(f) The life of the flexible tube and end closure assemblies shall be 10 yr from the date of manufacture or on completion of the allowable number of pressure cycles stated in section 6 of this Case, whichever is achieved first.
(g) The design operating temperature range shall be from 0°F to 100°F (−18°C to 38°C).
(h) The design storage temperature shall range from −10°F to +150°F (−23°C to +66°C) using the storage cases supplied with the PVHO.
(i) The pressurizing gas shall only be air, and a label to this effect shall be suitably displayed.
(j) The breathing gases, oxygen or air, shall be supplied to the occupant(s) of the PVHOs through BIBS masks or hoods. The operator shall select the breathing gas supply from the external control box. The operator shall also ensure that sufficient gases are available for flushing the PVHO if necessary and there shall be sufficient emergency gas supplies to complete the proposed treatment safely. All exhaled gases shall leave the PVHO via an overboard dump.
(k) All PVHOs shall have fire protection as specified in the relevant section of PVHO-1–2012 (Sections 5 and 6).
**Fig. 12-1 Typical Configuration**

**Detail of Assembly (No Tension)**

- Outer cover (a)
- Fabric folded over end of braid and stitched
- Braid inner
- Braid outer (b)
- Bladder (c)
- Window protection ring (e)
- Acrylic window (g)
- Stainless steel screw
- Aluminum clamp plates (d)
- Flexible LCP fiber ring (f)
- Cover drawcord
- Elastic mesh cover

**End View (Cover Removed for Clarity)**

**Section D-D (Cover in Situ)**
Table 12-1

<table>
<thead>
<tr>
<th>Diameter Range, in.</th>
<th>Maximum Number of Occupants</th>
<th>MAWP Range, psig</th>
<th>PVHO Service</th>
<th>Breathing Gas Outlets</th>
</tr>
</thead>
<tbody>
<tr>
<td>23–30</td>
<td>One</td>
<td>33.5–75</td>
<td>Diving (Section 6) and Medical (Section 5)</td>
<td>1</td>
</tr>
<tr>
<td>30–48</td>
<td>One</td>
<td>33.5</td>
<td>Diving (Section 6) and Medical (Section 5)</td>
<td>1</td>
</tr>
<tr>
<td>36–48</td>
<td>Two</td>
<td>33.5</td>
<td>Diving (Section 6) only</td>
<td>2</td>
</tr>
</tbody>
</table>

(l) All two-occupant PVHOs shall carry a hyperbaric fire extinguisher.

A User’s Design Specification shall be developed or provided for each model.

2 MATERIALS

Materials shall meet PVHO-1–2012, subsection 1-6 with the exception of the flexible tube that shall conform to Table 12-2 (see also Table 12-3). All of the materials of the flexible tube shall be used in combination to meet the performance requirements of this Case. A Process Control Procedure in accordance with para. 5.7 shall identify how the materials are to be used and in what specific quantities.

All materials used in the manufacture of the flexible tube shall be supplied with supporting documentation consistent with the requirements of the Quality Management System detailed in section 5 of this Case. Each lot used in the manufacture of the flexible tube shall meet those properties listed.

Material shelf life shall be identified as being suitable for long-term storage between uses and shall not exhibit visual or performance deterioration through aging for the entire life of the PVHO. The PVHO shall be stored in cases that meet the sealing requirements of IP67 and DEF STAN 81-41.

3 DESIGN AND MANUFACTURE

3.1 Design

The PVHO and associated systems shall be designed in accordance with PVHO-1–2012 and this Case.

3.2 Requirements

In subsection 1-7 of PVHO-1–2012, the design and manufacture of the PVHO and associated systems shall only be in accordance with paras. 1-7.4 to 1-7.11 and the following requirements:

(a) A detailed stress analysis shall be performed by a Professional Engineer registered in one or more U.S. states or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, who is experienced in composite pressure vessel design and construction.

(b) The stress analysis shall include full geometric modeling and a detailed finite element analysis of the PVHO and the flexible tube-to-window interface during assembly and disassembly, and under varying pressures up to a minimum of 6 times the MAWP. The loads applied by lifting handles, straps, and slings, as well as the position and weight of the occupants, shall be considered.

(c) The design analysis shall consider the effects of aging of the tube materials plus the effects of folding, unfolding, and long-term storage of the components. The design shall ensure that no damage will occur to any of the tube components by acute bending or by bending at less than the minimum bend radius for each component. Acute bending is defined as a bend in the LCP braid or the flexible membrane at an inside angle of less than 5 deg. The minimum bend radius for the fiber or flexible membrane shall be no less than 0.05 in. (1.25 mm).

(d) There shall be no penetrations in the pressure-retaining section of the flexible tube of the PVHO.

(e) The design and manufacturing process shall produce a flexible tube such that the assembly will not be damaged by the assembly process, pressurization, disassembly, or storage of the PVHO.

(f) The MAWP shall be the lesser of 75 psig or one-sixth of the proof pressure test results.

(g) The windows shall meet the requirements of PVHO-1–2012, Section 2, with the exception of para. 2-2.9. The design of the viewport flange shall be conducted as a part of the stress analysis requirement of para. 3.2(b) of this Case. The windows shall have standard window geometry (spherical sector with square edge) and qualify to meet the in-service guidelines of PVHO-2–2012.

(h) The windows shall be fitted with a nylon protection ring secured to the windows with a retainer rigidly attached to the protection ring and sealed with an O-ring. The protection ring shall seal against the flexible membrane of the tube.

(i) In lieu of the requirements of para. 4-9.6.1 of PVHO-1–2012, the number of occupants shall be defined by the number of breathing gas outlets supplied and as defined in the manufacturer’s specification.

(j) In lieu of the requirement of para. 6-3.1(b) in PVHO-1–2012, the minimum internal circumference of
### Table 12-2 Structural Nonmetallic Materials of Construction — Pressure Tube

<table>
<thead>
<tr>
<th>Component</th>
<th>Material/Material Properties</th>
<th>Typical Values</th>
<th>Test Procedure or Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane</td>
<td>Double-sided aromatic polyether polyurethane-coated nylon fabric</td>
<td>Fabric: high tenacity 940 dtex polyamide Threads: 11/cm warp, 10/cm weft Wt. 205 ± 10 g/m² Base nylon fabric to be scoured and heat set Coating/side: 0.2 mm Total thickness: 0.70 mm (nominal) Total weight: 0.73 kg/m² Tensile strength: Warp min. 2 850 N/5 cm Weft min. 2 400 N/5 cm Tear strength: Warp min. 1 600 N/5 cm (chisel cut) Weft min. 1 400 N/5 cm Adhesion (min.): 250 N/5 cm Cold resistance: −30°C ± 5</td>
<td></td>
</tr>
<tr>
<td>Braided main tube and end ring</td>
<td>Liquid crystal polymer (LCP) fiber filament yarn</td>
<td>1500 denier 300 filaments/yarn Density: 1.4 g/cm³ Tensile strength (±10%): 3.2 GPa, 25.9 g/denier, 465 ksi Tensile modulus: 75 GPa, 600 g/denier, 10,760 ksi Equilibrium moisture regain &lt; 0.1%</td>
<td></td>
</tr>
<tr>
<td>Outer cover and braid end fabric</td>
<td>PU-coated woven polyester fabric cover and braid end fabric</td>
<td>Base fabric: mass 180 g/m² Threads: 17/cm warp, 13/cm weft Coated fabric: total mass 240 /– 10 g/m² Tearing strength: ≥75 N across warp, ≥85 N across weft Tensile strength: ≥1 800 N/50 mm warp, ≥1 200 N/50 mm weft</td>
<td></td>
</tr>
<tr>
<td>Handle straps and lifting slings</td>
<td>Nylon webbing with stainless steel fittings</td>
<td>Structural items — not pressure boundary items</td>
<td></td>
</tr>
</tbody>
</table>

GENERAL NOTE: For brief description of test procedures and specifications listed in this table, see Table 12-3.

### Table 12-3 Test Procedures and/or Specifications Listed in Table 12-2 or Referred to in Case 12

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM D885-07</td>
<td>Standard test methods for tire cords, tire cord fabrics, and industrial filament yarns made from man-made organic-based fibers</td>
</tr>
<tr>
<td>ISO 1421:1998</td>
<td>Rubber- or plastic-coated fabrics for determination of tensile strength and elongation at break</td>
</tr>
<tr>
<td>ISO 1492-1:2000+A1</td>
<td>Textile slings</td>
</tr>
<tr>
<td>ISO 4674-1:2003</td>
<td>Rubber- or plastic-coated fabrics</td>
</tr>
<tr>
<td>ISO 13934-1:1999</td>
<td>Textiles</td>
</tr>
<tr>
<td>DEF STAN 81-41 Pt. 1 Issue 6, including STANAG 4280</td>
<td>Ministry of Defense — Packaging of Defense Material</td>
</tr>
<tr>
<td>93/42/EEC</td>
<td>European Council directive concerning medical devices</td>
</tr>
</tbody>
</table>
the flexible entry to the PVHO shall be 56 in. (142 cm), when the maximum overall diameter of the PVHO is less than 23.5 in. (600 mm).

(k) All load-bearing lifting handles, straps, and slings shall be designed to meet the requirements of EN1492-1:2000 and be labeled. The number of occupants shall be taken into account.

(l) Any changes to the design, materials, or manufacturing procedures of the nonmetallic components of the flexible tube shall be cause for prototype retesting.

3.3 Design Certification

Conformance of the design of the PVHO to the requirements of PVHO-1–2012 shall be established by one of the two following procedures:

(a) A Professional Engineer registered in one or more U.S. states or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, who is experienced in composite pressure vessel design, shall certify that the PVHO was designed either by him or under his direct supervision, or that he has thoroughly reviewed a design prepared by others, and that to the best of his knowledge, the PVHO complies with PVHO-1–2012 and this Case.

(b) The design of the PVHO shall be reviewed by an independent third-party agency experienced in both nonmetallic pressure vessel design and PVHO systems, and as such, the organization shall provide a certificate that the PVHO complies with PVHO-1–2012 and this Case.

3.4 Manufacture

The tube shall be manufactured in accordance with a detailed process control plan.

The process control plan shall clearly define the details of the manufacturing steps necessary to fabricate the flexible tube and shall document the fabrication process. Any anomalies found during the manufacturing process shall be fully documented and may be corrected according to the process control repair plan. Any production testing already completed shall need to be repeated.

The materials and manufacturing processes used for production units shall be identical to those used for the tested prototypes.

4 TESTING

All prototype testing shall be witnessed by an independent third-party certifying agency experienced in composite pressure vessel technology. In lieu of the testing requirements of PVHO-1–2012, the requirements in paras. 4.1 and 4.2 of this Case shall apply.

4.1 Prototype Testing

(a) Pressure Proof Test. Hydrostatic proof tests shall be performed on at least three completely assembled PVHOs of the same design, shape, and format at maximum operating temperature. Each PVHO shall be pressurized to 6 times the design pressure and held without failure for a period of 30 min. Failure of the acrylic window assembly or the release of a window through the ends of the flexible tube shall be cause for failure of the prototype design. Should higher pressures be achieved, then the MAWP of the PVHO may be calculated using the applicable statistical analysis method defined in para. D-7 of Nonmandatory Appendix D.

Regardless of test results, the MAWP defined in para. (a) above shall not be exceeded. The outer protective cover may be removed from the assembled PVHO for the pressure proof tests in order to visually record and identify the mode of failure.

(b) Drop Test. A drop test of at least one complete PVHO of each size on concrete shall be conducted without failure. The PVHO shall be fitted with end closures and loaded with 200 lb (90 kg) of bagged sand per occupant and then pressurized to the MAWP. The PVHO shall be inclined at 45 deg and elevated to a height such that the minimum distance to the concrete impact surface is 3 ft (92 cm) and then dropped. No leakage, damage, or permanent distortion of the PVHO is permissible.

(c) Cyclic Hydrostatic Test. A cyclic hydrostatic pressure test of each size of completely assembled PVHO shall be conducted for between 4,000 and 10,000 cycles. The test shall comprise pressurization from 2 psig (or less but sufficient to ensure that the end closures remain sealed) to the MAWP and back to 2 psig at maximum operating temperature.

The duration of a cycle shall be determined by adding the times for the two tests described in (1) and (2) below.

(1) To establish the time for the pressure cycle, a hydrostatic test shall be conducted on the PVHO to determine the time taken for pressurization from ambient pressure to MAWP, plus the time taken for any changes in volume, caused by stress settlement, to subside.

(2) To establish the time for the depressurization cycle, a hydrostatic test shall be conducted on the PVHO to determine the time taken for depressurization from MAWP to ambient pressure, plus the time taken for any changes in volume, caused by stress relaxation, to subside.

To establish the maximum number of cycles satisfactorily completed on the unit under test, the pressure-retention properties of the vessel shall be checked every 2,000 cycles for leakage or any damage to any component of the pressure-retaining parts of the PVHO. Should leakage occur during cyclic testing, or at a cyclic level, then the maximum number of cycles achieved at the previous cyclic level shall be defined as CT and be used to determine the number of approved operational cycles (CA) for the PVHO using the following calculation:

\[ CA = (CT/2) - 1,000 \]
(d) **Extended-Duration (Creep-Rupture) Test.** A fully assembled pressure-retaining part of the PVHO shall be subjected to proof pressure testing at a pressure of 5 times the MAWP of the PVHO at maximum operating temperature for a period of at least 300 hr.

If at the completion of testing the following criteria are met, the PVHO shall be considered to have acceptable creep behavior:

A straight line shall be plotted using semi-log coordinates with pressure on the linear scale \((y)\) and time on the logarithmic scale \((x)\). The beginning coordinate of the line shall be the pressure at 0.1 hr and the MAWP multiplied by 9. The end coordinate on the line shall be twice the MAWP at 80,000 hr. A straight line shall be drawn through these two coordinates. This line represents the minimum pressure-time acceptance line. Failure to the left and below the pressure-time acceptance line is disallowed.

(e) **Cold Storage Test.** A test shall be conducted at least twice, demonstrating that the pressure-retaining part of the PVHO can be assembled and inflated at minimum operating temperature. The PVHO shall be folded and stored for a minimum of 8 hr at minimum operating temperature immediately prior to the commencement of the tests.

(f) **Off-Gassing Toxicity Test.** An off-gassing toxicity test shall be carried out that meets the requirements of subsection 1-10 of PVHO-1–2012.

(g) **Cyclic Folding Test.** A folding and unfolding test shall be carried out on the flexible tube of the PVHO for a minimum of 4,000 cycles. At the end of the test, the tube shall be inspected to ensure that there is no damage, delaminations, or other defects to any of the components of the flexible tube or cover.

(h) **Puncture Test.** A puncture test using a \(3/8\)-in. (10-mm) wide flat screwdriver shall be performed on one PVHO at MAWP. The force to puncture the bladder shall be at least 225 lb (102 kg). After the screwdriver punctures the PVHO body, there shall be no tearing or rapid decompression.

Flexible tube and viewport components used in prototype testing above shall not be used in production PVHOs.

### 4.2 Production Testing

Every completely assembled PVHO shall be subjected to a pneumatic test at a pressure of 1.5 times the MAWP and held for a period of 1 hr with a permissible leakage rate of 2% per hour. Internal and external air temperatures shall be measured and recorded at the beginning and end of each test so that compensation may be made for any temperature differences.

Every PVHO shall be examined visually and dimensionally for damage following each test. Cracks, permanent deformations, or other signs of damage shall be grounds for rejection of the PVHO.

### 5 QUALITY ASSURANCE

#### 5.1 General

PVHOs built to this Case shall be built by manufacturers whose Quality Management System is approved and certified by a certified body as meeting the requirements of ISO 13485:2003 and European Directive 93/42/EEC Annex II (excluding Section 4) for Medical Devices. In addition, the requirements of Section 3 of PVHO-1–2012 shall be met in full.

A documented Quality Assurance Plan (QAP) shall be developed for the design and manufacture of the PVHO. This section describes the requirements of the content of the QAP.

#### 5.2 Organization

The QAP shall describe the organizational structure, with responsibilities, authorities, and lines of communication clearly delineated. Persons shown in the QAP to be responsible for verifying the PVHO quality shall have the authority and organizational freedom to

- (a) identify problems affecting quality
- (b) initiate, recommend, or provide solutions to quality problems through designated channels
- (c) verify implementation of solution
- (d) control further processing, delivery, or assembly of a nonconforming item, deficiency, or unsatisfactory condition until proper corrective action has been taken

#### 5.3 Design Control

A methodical process shall be used to develop and control the PVHO design, which includes

- (a) a process for design inputs and review
- (b) a requirement for formal design review
- (c) a process for product configuration management and change control

#### 5.4 Document Control

The QAP shall describe the manufacturer’s measures for ensuring that design output documents are correctly translated into manufacturing specifications, drawings, procedures, and shop/lab instructions. Considerations shall be made for reviews and approvals, including those of the purchaser.

The manufacturer shall include the procedure for ensuring distribution of appropriate documents to the working areas in a timely fashion and the process for ensuring nonuse of obsolete documents.

#### 5.5 Procurement Control

The QAP shall include the controls necessary to ensure that applicable requirements are included in procurement documents. The manufacturer shall describe the basis for source evaluation and selection and the method of objective evaluation of the quality of furnished materials, items, and services upon receipt.
5.6 Material Control

The QAP shall describe the identification applied to material and items upon receipt and shall show that this identification shall remain until the material or item is incorporated into the PVHO. Identification shall be such that the manufacturer’s personnel can easily determine quality status, material or item type, specification, lot or part as appropriate, and job number.

All material properties of production units shall meet or exceed the actual material properties of the prototype test articles.

5.7 Process Control

The QAP shall include a Process Control Procedure that shall record the identification of materials and items incorporated into the PVHO and each chronological step in their manufacture, including inspection and test steps. The Process Control Procedure shall contain periodic operator and inspector signature points so that product status can be readily determined.

The manufacturer shall identify critical manufacturing activities and ensure that they are accomplished by appropriately trained and qualified personnel. Inspection points shall follow the activities in the process control plan.

5.8 Inspection Control

The QAP shall include the measures used by the manufacturer to ensure that inspections are reliable. These measures shall include:

(a) proper qualification of inspection personnel
(b) calibration of inspection instrumentation
(c) incorporation of acceptance criteria into inspection points in the process control plan
(d) assurance that inspections are performed by persons other than those performing or supervising work
(e) documentation of all inspections

5.9 Test Control

The QAP shall describe the measures used to ensure that tests (including lab tests) are performed consistently and reliably. The following requirements shall be met:

(a) Tests shall be performed in accordance with written instructions stipulating acceptance criteria.
(b) Test results shall be documented.
(c) Examination, measurement, and testing equipment used for activities affecting quality shall be controlled, calibrated, and adjusted at specified periods to maintain required accuracy.
(d) Tests shall be performed by trained and qualified personnel.
(e) Tests shall be verified by persons other than those performing or supervising the test.

5.10 Control of Measuring Test and Inspection Equipment

The QAP shall describe the equipment used in inspections and tests and the measures used to ensure appropriate accuracy. Appropriate equipment shall be calibrated, and the calibration shall be traceable to standards where they exist. Where such standards do not exist, the equipment manufacturer’s recommendations shall be followed.

5.11 Control of Nonconforming Items/Materials

The QAP shall describe the measures used by the manufacturer to control materials or items that are found to be discrepant to prevent their inadvertent use. Nonconforming materials/items shall be identified. The discrepant condition(s) shall be documented. The process for determining, documenting, and verifying corrective action shall be described, including the involvement of the purchaser.

5.12 Quality Assurance Records

The QAP shall provide for quality assurance records.

(a) Records shall be specified, compiled, and maintained to furnish documentary evidence that services, materials, and completed PVHOs meet this and applicable referenced standards.
(b) Records shall be legible, identifiable, and retrievable.
(c) Records shall be protected against damage, deterioration, or loss.
(d) Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.
(e) Records required for traceability shall be retained for a minimum of 12 yr.

5.13 Standard Repair Planning

The QAP shall describe methods for repairing discrepancies that are expected to occur during the PVHO manufacture.

5.14 Quality Assurance Overview by an Independent Third Party

An independent third-party agency shall be employed to ensure that all PVHOs under this Case are designed and manufactured to the requirements of PVHO-1–2012 and this Case. This includes, but is not restricted to, the following:

(a) The PVHO is designed in accordance with PVHO-1–2012 and this Case.
(b) The manufacturer is working to the requirements of the quality control system.
(c) The materials used in construction of the PVHO comply with approved procedures by qualified operators, as required by PVHO-1–2012 and this Case.
Fig. 12-2  Example Marking of Case 12 PVHO

<table>
<thead>
<tr>
<th>PVHO-1–2012 (Case 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certified by</td>
</tr>
<tr>
<td>______________________</td>
</tr>
<tr>
<td>(name of manufacturer)</td>
</tr>
<tr>
<td>______________________</td>
</tr>
<tr>
<td>psi/MPa/msw/fsw internal</td>
</tr>
<tr>
<td>(maximum allowable working pressure)</td>
</tr>
<tr>
<td>______________________</td>
</tr>
<tr>
<td>°F  °C</td>
</tr>
<tr>
<td>(operating temperature range)</td>
</tr>
<tr>
<td>______________________</td>
</tr>
<tr>
<td>(manufacturer's serial no.)  (year built)</td>
</tr>
</tbody>
</table>

Section (5 or 6 or 5 and 6)
[SINGLE-_OCCUPANCY, SECTION 5 (MEDICAL) AND/OR SECTION 6 (DIVING); DUAL-Occupancy, SECTION 6 (DIVING) only]

Number of Occupants
(1 or 2 occupants)

Fig. 12-3  Additional Markings for Case 12 PVHOs

<table>
<thead>
<tr>
<th>Overall chamber length</th>
<th>_______ in. _______ cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allowable number of pressure cycles: (as defined following prototype testing)</td>
<td></td>
</tr>
<tr>
<td>Allowable number of folding for storage cycles (as defined following prototype testing)</td>
<td></td>
</tr>
<tr>
<td>Flexible tube expiration date: (DD/MM/YYYY)</td>
<td></td>
</tr>
<tr>
<td>Storage temperature (min./max.): –10°F/+150°F –23˚C/+66˚C</td>
<td></td>
</tr>
<tr>
<td><strong>PRESSURIZE WITH AIR ONLY</strong></td>
<td></td>
</tr>
<tr>
<td><strong>CONSTANT SUPERVISION REQUIRED DURING TREATMENT</strong></td>
<td></td>
</tr>
<tr>
<td><strong>THIS EQUIPMENT IS ONLY TO BE OPERATED BY QUALIFIED PERSONNEL, FULLY AWARE OF THE PROCEDURES DETAILED IN THE MANUAL AND AS DIRECTED AND SUPERVISED. USE BY NONQUALIFIED PERSONNEL IS EXPRESSLY PROHIBITED</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DO NOT EXPOSE PVHO TO DIRECT SUNLIGHT OR UV LIGHT SOURCES FOR EXTENDED PERIODS</strong></td>
<td></td>
</tr>
</tbody>
</table>

(d) All manufacturing operations are conducted in accordance with approved procedures by qualified operators, as required by PVHO-1–2012 and this Case.

(e) All defects are acceptably repaired.

(f) All prototype and production testing has been performed and witnessed as required by PVHO-1–2012 and this Case.

(g) The PVHO is marked in accordance with PVHO-1–2012 and this Case.

(h) A visual inspection of the PVHO is conducted to confirm that there are no material or dimensional defects.

The manufacturer shall arrange and give the third-party inspection agency free access to all facilities associated with the manufacture of the PVHO. The manufacturer shall keep the third-party inspection agency informed of the progress of the work and shall notify them reasonably in advance when PVHOs will be ready for any required tests or inspections.

6 MARKING

(a) In lieu of PVHO-1–2012, subsection 1-9, a label shall be permanently and rigidly attached to the outside surface of the flexible tube and shall be permanently marked, close to one end, with the data required in PVHO-1, para.1-9(a) and the information shown in Fig. 12-2.

(b) In addition to the above, the PVHO and/or its control box shall be prominently marked as shown in Fig. 12-3.

(c) The PVHO shall also indicate, by description or geographically, items that shall not be permitted in the chamber. These should include cell phones; electronic devices (especially those using lithium batteries); flammable items such as matches, lighters, and hand warmers; and sharp objects such as needles and knives.

(d) PVHO-1 Case 12 Form, Manufacturer’s Data Report for Pressure Vessels for Human Occupancy, shall be completed to certify that each PVHO meets the requirements of PVHO-1–2012 and this Case.
PVHO-1 Case 12 Form
Manufacturer's Data Report for Pressure Vessels for Human Occupancy

1. Design criteria

2. Manufactured and certified by

3. Manufactured for

4. Vessel identification (manufacturer's serial no.) (year built)

5. The design, construction, workmanship, and chemical and physical properties of all parts meet the applicable material specifications of PVHO-1-_______ (year) and Case Nos. _________.

6. Manufactured for a maximum allowable working pressure of ______ psig ______ barg ______ msw ______ fsw, a maximum working temperature of ______°F ______°C and a pneumatic internal test pressure of ______ psig ______ barg ______ msw ______ fsw.

7. Design analysis conducted by

8. Designed for one occupant/one or two occupants (delete as applicable)

9. Windows: Certification Reports, properly identified and signed by the window fabricator, are attached for the following items:

<table>
<thead>
<tr>
<th>Nos.</th>
<th>Location</th>
<th>Type</th>
<th>Diameter</th>
<th>Nominal Thickness</th>
<th>How Attached</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Penetrator Plate No. _______________ Penetrator Blank No. _______________ Medlock No. _______________

CERTIFICATION OF DESIGN

User’s Design Specification on file at ________________
Manufacturer’s Design Report on file at ________________
User’s Design Specification certified by ___________________ State _______ Reg. no. ________________
Manufacturer’s Design Specification certified by ___________________ State _______ Reg. no. ________________
Prototype test program attested by ________________________
Quality Assurance Program reviewed by _____________________
Manufacturer’s documentation reviewed by _____________________ (name and date)
Production testing witnessed by ___________________________ (name and date)

CERTIFICATION OF COMPLIANCE

We certify that the statements made in this report are correct and that all details of the design, material, construction, and workmanship conform to the ASME Safety Standard for Pressure Vessels for Human Occupancy (PVHO-1) and PVHO Case 12.

Date ______________ Company name ___________________________ Signed ___________________________