Use of Nylon-Jacketed, Aliphatic Coated Bladder, Zipper Closure Cylindrical Vessels in the Construction of PVHOs under PVHO-1

Approval date: March 19, 2015
Expiration Date: March 19, 2021

Inquiry: Under what conditions may a portable flexible nylon-jacketed, aliphatic coated bladder with zipper closures be constructed under the rules of PVHO-1: 2012?

Reply: It is the opinion of the Committee that portable flexible nylon-jacketed, aliphatic coated bladder type cylindrical vessel with zippered closures may be constructed under the requirements of PVHO-1 and be marked as a PVHO, when the requirements of PVHO-1, with the following exceptions and additions, have been met:

1.0 GENERAL
The PVHO chamber shall be a flexible composite cylinder consisting of an inner bladder (see Dwg15C37195), an outer jacket, and webbing secured with mechanical safety buckles. The bladder and jacket are closed with three overlapping zippers that provide an initial pressure seal. Two adjacent transparent windows permit viewing of the occupant. Connections for pressurization and breathing gas may only be located at the ends. The window shield (clear viewport retaining cover) (see Section A-A) is supported by the jacket and webbing.

The chamber shall be pressurized with a continuous flow of air that shall be expelled through a ventilation valve. The PVHO and associated systems shall be designed, constructed, inspected, tested, marked (and installed if applicable) to ASME PVHO-1-2012 Edition, Sections 1,2,3,4, and 5 with exceptions and additions detailed in this Case.

The following sections/paragraphs of PVHO-1-2012 are not applicable to vessels built under this Case Section 2-2, 2-7, 2-8 and 2-10
Section 5-5.7
Section 6
Section 1-6, 1-7.1 thru 1-7.3, 1-7.5, 1-7.8,
1-7.11 thru 1-7.16
Section 7

A User’s Design Specification shall be provided. The User’s Design Specification shall include the following data:
a) Maximum number of occupants is one
b) This PVHO is not intended for transport under pressure
c) The maximum allowable working pressure (MAWP) shall be 8 psig (0.55 bar)
d) Pressurization gas shall only be air and a label to this effect shall be suitably displayed, and an exhaust valve and an ASME overpressure relief valve shall be fitted with a “gag” device operable from outside the chamber
e) The breathing gas supplied to the occupant of PVHO shall be 100% oxygen through a BIBS mask or hood. The operator of the PVHO shall have external control of the supply of breathing gas. The operator shall ensure that sufficient gas is available for flushing the PVHO if necessary, and have sufficient emergency gas available to complete the proposed treatment safely. All exhaled gas shall leave the PVHO via an overboard dump system. A table shall be provided to guide the user to the amount of gas required for a treatment over a period of time.
f) The pressurization/depressurization rates shall be no greater than 1 psi/min. In an emergency depressurization rate will not exceed two minutes.
g) Chamber managed flow rate shall not exceed 15 SCFH
h) The PVHO shall have two windows in the body of the chamber. The windows shall permit external viewing of the occupant’s head, face, chest and arms.
i) Maximum internal length shall be 97” (2.46m).
j) Internal diameter shall be 27” nominal (.69m).
k) Three overlapping zippers shall be used. The outer zipper is necessary for ease of preparing the gasket for inflation and would also prevent rapid air loss in the event of premature opening of the inner zippers.
The design temperature limits shall be 32° F to 100° F (0° C-37° C). The design storage temperature range shall be - 10° F (-12° C) to 150° F (65° C).

m) The number of pressure cycles shall not exceed 4000 cycles.

n) The design life is ten (10) years from the date of manufacture or on completion of the 4000 pressure cycles, or completion of the allowable number of folding cycles for storage, whichever occurs first.

o) Penetrators shall only be located in the ends. Two breathing gas penetrators shall be compatible with the BIBS or hood. One oxygen sensor penetrator shall be dedicated for monitoring internal PVHO atmosphere for excessive levels of O2 (MIN 18% - MAX 25%) and CO2. The monitor shall include an alarm alerting the operator when these levels are exceeded.

p) There is no temperature control. Patient comfort may be addressed by variation in air flow through the PVHO.

q) Fire suppression shall be provided by portable internal fire extinguisher approved for Military use (AMU), and/or internal fire suppression activated externally.

r) Environmental degradation allowance is required of stress boundary materials, using ASTM 751 or actual aged (equal to or greater than rated life) tensile strength values

s) Bladder joining shall be RF welding only. No adhesives are allowed except for sealing of exterior seams and repairs performed only by the manufacturer followed by post repair testing (see section 4.2 Production test)

t) The owner/operator shall maintain a detailed log book relating to each PVHO that clearly records the number of pressurizations, the maximum pressure achieved, the date, location and the reason for each use (i.e. testing, training, therapy, etc.) and record whether the PVHO was left assembled or packed in its case after use. Only mild detergent should be used to clean the window film and only Hyox may be used to decontaminate the interior bladder, but should not be allowed to pool on the surface of the chamber. Cleaning of the acrylic clear viewport retaining cover may be done with the use of aliphatic naptha or hexane.

u) Include temperature and humidity parameters, if any.

v) The owner/operator shall make regular inspections prior to each use inspecting the PVHO for any change in color of the bladder and or window, chalkiness on the surface, cracking or creasing along folds, damaged zipper teeth, fraying of any stitching, looseness in the bladder or discontinuity in construction or change in physical form, and if discovered, the PVHO should be removed from service and consult with the manufacturer for further evaluation.

w) The operator manual shall contain normal system operating procedures and emergency procedures that list specific actions in the event there becomes a problem with operation of the PVHO and associated systems. The emergency procedure objective shall provide an alternative line-up to safely depressurize and evacuate the occupant. An emergency procedure shall be for each support system failure (i.e. loss of gas supply, monitor, depth control, electrical, etc.) that would jeopardize the safety of the occupant or necessary to complete the treatment.

x) The operator manual will contain the following statement: “This equipment is only to be operated by qualified personnel fully aware of the procedures detailed in this manual, as directed and supervised at all times. Use by untrained or inexperienced personnel is expressly prohibited.”

2.0 MATERIALS:

Materials shall meet PVHO-1 2012, para. 1-6 PVHO Materials, and in lieu of the requirements of PVHO-1, Sections 1-6 and 2-2, 2-7, 2-8, and 2-10, the materials in Table 1 shall be used. All of the materials shall be used in combination to meet the performance requirements of this Case. A process control procedure in accordance with 5.7 shall identify how the materials are to be used and in what specific quantities. Stress boundary materials (bladder, jacket, and webbing assemblies) from each production lot shall undergo tensile coupon testing to insure materials meet or exceed actual prototype testing within the 90% confidence level (see para 5.6 Material Control) All materials used shall be supplied with supporting documentation consistent with the requirements of the Quality Management System detailed in Section 5 of this Case. Each “lot” shall meet the ASTM or Federal Standards material specifications as indicated. 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.
Material test reports to recognized testing procedures (i.e ASTM, Mil Specs) for the primary strength members, which are the webbing, jacket, buckles, bladder, window shield, film and penetrator flange shall include lot information and attach Material Safety Data Sheets (MSDS). Test conditions are 70°F ±10 °F (21° C) and 30–40%RH± 10%RH unless otherwise specified. The relevant strength data shall be recorded on the Manufacture’s Data Report. Any changes of primary strength material shall be cause for full prototype re-testing, unless it can be demonstrated to the satisfaction of a PE experienced in pressure vessel design that the integrity of the PVHO is not reduced.

Table 1 PVHO Materials of Construction
*Denotes test reports required and reported on Manufacturer Data Report

<table>
<thead>
<tr>
<th>Coated Bladder Fabric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Fabric: Polyethylene Terephthalate (PET) 1500 denier 13 oz – 15 oz, thread count 35/35 threads per inch.</td>
</tr>
<tr>
<td>No Pre-Treatment of Fabric.*test at 1 ATA with resistance comparable to standard automotive equipment.</td>
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<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>MIN</th>
<th>SPEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Breaking Strength: Warp</td>
<td>823 lbs/323 kg</td>
<td>ASTM-D 751 Procedure B</td>
</tr>
<tr>
<td>*Breaking Strength: Fill</td>
<td>712 lbs</td>
<td>ASTM-D 751 Procedure B</td>
</tr>
<tr>
<td>*Seam Adhesion RF</td>
<td>24 lbs / in</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>Low Temperature Bending</td>
<td>-40° C 12 hours</td>
<td>ASTM-D 2136</td>
</tr>
<tr>
<td>Elongation: Warp Max</td>
<td>37%</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>Elongation: Fill Max</td>
<td>49%</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>*Bursting Strength Ball</td>
<td>650 Kg</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>Puncture Resistance</td>
<td>441 lbs</td>
<td>FED STD 101-2031</td>
</tr>
<tr>
<td>Tear Strength</td>
<td>110 lbs</td>
<td>ASTM-D 751 Procedure B</td>
</tr>
<tr>
<td>Low Temperature Crack Resistance</td>
<td>-40° C</td>
<td>ASTM D 2136</td>
</tr>
<tr>
<td>Accelerated Heat Aging by the Oven Method Max</td>
<td>7% loss in burst strength</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>Block Resistance Max</td>
<td>160° F (71° C)</td>
<td>ASTM-D 751</td>
</tr>
<tr>
<td>Abrasion Resistance</td>
<td>&gt; 3000 cycles to expose fabric</td>
<td>ASTM-D 3389</td>
</tr>
<tr>
<td>Air Porosity</td>
<td>10 min at 7psi</td>
<td>B.S. 4F 100 clause 32.1</td>
</tr>
<tr>
<td>Flame Resistant</td>
<td>102 mm/min Max burn rate</td>
<td>FM MVSS 302*</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Nylon Jacket: The outer cover shall be woven nylon 11-13-oz/sq yd (.31-.37 kg) finished meeting Mil-C-12369F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II Ballistic Nylon heat set and scoured (with the following exceptions: No ballistic resistance required; no fiber identification nor marking required (3.14 and 3.15); no infrared requirements.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>MIN</th>
<th>SPEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breaking Strength: Warp</td>
<td>840 lbs (381 kg)</td>
<td>ASTM-D 5034</td>
</tr>
<tr>
<td>Breaking Strength: Fill</td>
<td>700 lbs (317 kg)</td>
<td>ASTM-D 5034</td>
</tr>
<tr>
<td>Tear Strength: Warp</td>
<td>155 lbs (70 kg)</td>
<td>ASTM-D 2261-96</td>
</tr>
<tr>
<td>Tear Strength: Fill</td>
<td>155 lbs (70 kg)</td>
<td>ASTM-D 2261-96</td>
</tr>
<tr>
<td>Polyurethane Coating</td>
<td>1 oz (29 ml)/sq.yd</td>
<td></td>
</tr>
</tbody>
</table>

| Clear Polyester Polyurethane Film Window: .060 thick, +/- .005 |

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>MIN</th>
<th>SPEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness</td>
<td>90-95 Shore A</td>
<td>ASTM-D 2240</td>
</tr>
<tr>
<td>Ultimate Tensile Strength</td>
<td>1”x1” 5000 lbs</td>
<td>ASTM-D 412 Method A</td>
</tr>
<tr>
<td>Ultimate Elongation Max</td>
<td>400%</td>
<td>ASTM-D 412</td>
</tr>
<tr>
<td>Tear Resistance</td>
<td>650 lbs per inch (295 kg/25)</td>
<td>ASTM-D 624 Doe C</td>
</tr>
</tbody>
</table>

| Low Temperature Bending                 | 12 hours @ -20°F | DIN 53546 Film       |
**Acrylic Window Shield:** The window shield material shall be in accordance with Acrylic Plastic per ASTM D 4802-02. However, the window, which is a sector of a cylinder and is supported by fabric and webbing is a nonstandard window. The test program in Section 4 exceeds the requirements for STPP in Section 2-2.6 of PVHO-1 and is an alternative to the requirements for determination of LTPP and CPP Thickness 3/8”.

**Zipper Closures** to meet Federal Spec CID A-A-55634A 011-03 CEF P09F 54 & 011-03 CEF P10P 54
Note: zipper manufacturer to supply C of C to this CID

**Webbing, Polyester** - 2.42 oz/yd 0.07”(1.7 mm) thick 2”(50 mm) wide

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>MIN</th>
<th>SPEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breaking Strength</td>
<td>6,000 lbs(2,721 kg)</td>
<td>Tested to Web Sling and Tie</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Down Association T-4 or Fed Std 191A Method 4108</td>
</tr>
</tbody>
</table>

**Silicone Rubber** – Durometer 30 Shore A, ASTM D 2240

**Safety Buckle** – Minimum Breaking Strength of 3,360 pounds (1,524 kg) FMVSS 571.209

**Polyester Thread 4 Cord** (Tex 270) Type 2 Class 1 and FF (Tex 90) Type 1, Class MIL-DTL-32072.

**Penetrator Flange:** Texin 950 aromatic polyether-based thermoplastic polyurethane with Shore D hardness of 50.

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>MIN</th>
<th>SPEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength</td>
<td>6,000 psi</td>
<td>ASTM-D 412</td>
</tr>
<tr>
<td>Tensile Strength C 100% elongation</td>
<td>2,000 psi</td>
<td>ASTM-D 412</td>
</tr>
<tr>
<td>Threads of Flange – aluminum 6061 –T6511</td>
<td></td>
<td>ASTM B221-02QQ-A200/8</td>
</tr>
<tr>
<td>Anodized to</td>
<td></td>
<td>MIL-A 862F Ty 2 Class 2</td>
</tr>
</tbody>
</table>

### 3.0 DESIGN AND FABRICATION

In lieu of PVHO-1-2012 Section 1-7, the design and fabrication of the PVHO and associated systems shall be in accordance with this Case and the following requirements. Any changes to the geometry, size, materials, design or manufacturing procedures of the PVHO shall be cause for full prototype re-testing, and shall be submitted as a new Case, unless it is demonstrated to the satisfaction of PE experienced in pressure vessel design that the integrity and factor of safety of the PVHO is not reduced.

#### 3.1 Design Analysis

A stress analysis shall be performed by a Professional Engineer registered in one or more of the states of the United States of America, or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, and who is experienced in composite pressure vessel design and construction. The Designer shall consider the effects of material degradation due to environmental considerations both operational and non-operational shall be accounted for. Included in the analysis will be an analysis, fabrication, testing, and certification of piping and controls system per PVHO-1 2012 including Section 4 and system documentation required per 1-7.9

#### 3.2 Design Risk Analysis

The designer and manufacturer shall institute a comprehensive risk management plan in accordance with ISO 14971:2007 and IEC 60601-1, and Section 1-11 Risk analysis to PVHO-1 2012 In addition, oxygen hazards and fire risk analysis shall be undertaken using recognized standards ASTM G63, G128 and G88. These processes, if they identify protective measures to be implemented, shall be actioned for eliminating, reducing or mitigating risks to within specified acceptable levels per ISO 14971. Warning labels shall be prominently displayed outside the chamber listing prohibitive materials that have been classified as dangerous such as hand warmers and any electrical device. A detailed risk analysis shall be performed of any quick disconnect hoses and use of interlock fitting if practical to prevent accidental disconnection.
3.3 Requirements

a) The MAWP shall be 8 psig (0.55 Bar) at 100° F (37.8° C).

b) Temperature range shall be between 32° F and 100° F (0° and 37.8° C)

c) The MAWP shall be based on testing three prototypes to at least six (6) (plus rated life aging degradation factor). The MAWP shall be verified by prototype testing and the resulting proof pressure shall exceed the MAWP and aging degradation factor as follows: This testing applies the Statistical Method IV of D-7.4 and adds a maximum degradation after ten years of 7% to the MAWP. For three chambers, the proof pressure shall exceed 6.42 times the MAWP and for four chambers, the proof pressure shall exceed 5.35 times MAWP.

d) The design analysis shall consider the effects of aging of the stress boundary material, plus the effects of folding, unfolding, and long term storage of the collapsed chamber. The design shall ensure that no damage will occur to the cloth within the composite shell by acute bending is defined as a bend in the cloth shell at an inside angle of less than 5 deg. The minimum bend radius for the cloth shall be no less than 0.05 in. strength reduction due to sewn connections shall be based on test data and included in the analysis. Procedures are to be written as to the type of stitch, length of stitch, stitch patter size, type and size of thread, and results from the break test. Two test coupons from each joint type of the bladder both heterogeneous and homogeneous dielectric welds will be performed and recorded verifying min material adhesion specification for each PVHO and lot of material used.

e) All penetrators shall be located in the ends.

f) The two windows shall be located in the cylindrical portion of the shell.

3.4 Design Certification

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

a) A Professional Engineer (PE) registered in one or more states of the United States of America, or the provinces of Canada, or licensed by any other country that has equivalent licensing procedures, and who is experienced in composite pressure vessel design shall certify that the PVHO was designed either by the PE or under the PE’s direct supervision, or that the PE has thoroughly reviewed a design prepared by others, and that the PVHO complies with PVHO-1 and this Case.

b) The design of the PVHO shall be reviewed by an independent third party agency independent of the designer, fabricator, and user, who is qualified through education, test, or experience to perform the inspection, and such individual or organization shall provide a certificate that the PVHO complies with PVHO-1-2012 Case XX

3.5 Fabrication

The PVHO 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 PVHO, 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. (See 5.13 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.

4.0 TESTING

All prototype testing shall be witnessed by an independent third party, independent of the designer, fabricator, and user who is qualified through education, test or experience to perform inspection. In lieu of the testing requirements of PVHO-1-2012, the following requirements shall apply:

4.1 Prototype Testing

Deviation from established design parameters, geometry, size, materials of construction, or fabrication process shall require a new prototype qualification test be conducted, unless it is demonstrated to the satisfaction of PE experienced in pressure vessel design that the integrity and fact of safety of the PVHO is not reduced. PVHO’s used for prototype testing will not be used other than for testing.
a) **Proof Pressure Test:**
1) Proof pressure tests shall be conducted on a minimum of three (3) full scale prototype chambers. These prototypes shall be full size and of identical construction to the end-item, with all fabrication completed which in any manner may affect the integrity of the pressure boundary.

2) The rated pressure shall be based on a minimum 6:1 ratio of proof pressure determined by testing three prototype chambers to at least 48 psig (3.3 bar) for 30 minutes.(if four prototypes are tested (per the Non-Mandatory Appendix) than the rated pressure shall be based on a minimum 5.35:1 ratio of proof pressure or 42.8 psig (includes aging degradation allowance)) Rated pressure testing shall be performed at the most critical service temperature of 100° F (37.8° C). No damage, permanent distortion or increased ventilation rate of the PVHO is permissible, represented by tearing or looseness of seams causing excessive air leakage beyond 1 psi/minute

3) The material in the primary strength members shall be tested to determine actual breaking strength. The test data shall be recorded and retained.

b) **Drop Test:**
A drop test of at least one full-scale PVHO on concrete shall be conducted without failure. The PVHO shall be loaded with an evenly distributed load of 200# (90 kg) of bagged sand and then pressurized to the rated pressure. The PVHO shall be inclined at 45° elevated to a height such that the minimum distance to the concrete impact surface is 3 ft. (1 m) and then dropped. The chamber will then be inverted (opposite end impacted) and dropped again. No damage, permanent distortion or increased ventilation rate of the PVHO is permissible, represented by tearing or looseness of seams causing excessive air leakage beyond 1 psi/minute

c) **Cyclic Pressure Test:**
The maximum permissible number of design cycles shall be determined by cyclic testing of a full scale PVHO.

1) The cyclic pressure test shall be from 0 ambient of MAWP and back to 0 ambient. The PVHO shall be pressurized to MAWP and the time when expansion ceases shall be measured. This time shall be doubled and the greater of the doubled time or 1 minute shall be used as the minimum hold time at pressure. Cyclic testing shall be performed at the most critical service temperature of 100° F (37.8° C).

2) The number of approved operational cycles (CA) shall be computed as (CA) = (CT/2)-1000, where CT = total number of test cycles performed. The chamber will be cycled for a minimum of 10,000 cycles. Every 2000 cycles the PVHO shall be visually inspected for damage and excessive air flow rate. The requirement for acceptance of the cyclic pressure test is that no crack (or other damage) shall be visibly detectable, using methods that are normally used for visual inspection of the applicable material. In addition, the air flow rate required to maintain pressure shall not exceed 1 psi/minute.

d) **Creep Test:** Extended time tests of three(3) completely assembled PVHOs that have either undergone proof pressure testing without failure or alternatively have not been previously tested, shall be conducted at the most critical service temperature using the following criteria: (See Figure 1 Creep Test Acceptance Criteria)

1) A straight line shall be plotted using semi log coordinates with pressure on the linear scale (Y) and time on the logarithmic (x). The beginning coordinate of the line shall be the pressure at 0.1 hour and the MAWP multiplied by 9. The end coordinate on the line shall be twice (2) the MAWP at 80,000 hours. 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.

2) A test pressure shall be applied such that the time without failure shall exceed the line pressure-time acceptance line; however, the minimum time shall be at least 300 hours.

3) If all three (3) chambers exceed the 300 hours and exceed the minimum pressure-time acceptance line, the PVHO has acceptable creep behavior. (failure is loss of pressure > 10 psi/min).
e) **Cold Storage Test:** A cold storage test demonstrating that the chamber can be assembled and inflated at minimum operating temperature shall be conducted. The chamber shall be folded and stored for a minimum of 8hrs at -10° F ±10° -10° (5.5°C) and then inflated to operating pressure at 32° F ±10° -0° F (0° C) temperature in a period not exceeding 15 minutes. Repeat the cold storage test a minimum of two times. No increase in air flow rate to maintain air pressure beyond 1 psi/minute, damage in the form of tearing or looseness of seams, or permanent distortion is permissible.

f) **Cycle Folding Test:** A chamber will be subjected to 4,000 cycle folding exercises. The chamber will be unzipped and laid flat on a table at room temperature. The head end with the acrylic lens will be folded over onto itself once. The foot end will be folded onto itself twice. The final fold will be lifting the folded chamber onto the end cap. This will create a size suitable for storage in the carrying case. After this is completed, it will be unfolded to the flat position and zippers closed. Upon completion of the 4,000 cycles, the chamber will be pressurized to 1.5 x operating pressure and inspected for any defects such as fracturing of the material, delamination, wear or fracture of the zipper body. No damage or leaks beyond 1 psi/minute is permissible.

g) **Off-gas Test:** The off-gas requirements of Section 1-10 of PVHO-1 shall be satisfied.

h) **Puncture Test:** A puncture test using a 3/8” wide screwdriver, sharpened flat enough to penetrate the body of the shell, shall be performed on one PVHO at MAWP. The force to puncture the bladder shall be at least 255 lbs (115 kg). After the screwdriver punctures the PVHO body, there shall be no extensive tearing or rapid decompression greater than 10 psi/minute.

i) **Leakage Rate Test** – The leakage of each of the three prototype PVHOs used in the Pressure Drop Test shall be determined by pressurizing each PVHO to MAWP at room temperature for a period of 15 minutes and measuring the maximum flow rate of the gas required to maintain MAWP. The average of the three flow rates shall be the “normal” leakage rate used for comparison to production units. This test shall be performed using air.
j) **Pressure Drop Test:** Assuming a complete loss of pressurization or supply source during operation, conduct a pressure drop test by inflating to MAWP and shut off gas supply. The maximum allowable pressure drop shall be less than 50% of a pressure drop rate that would compromise the safety of occupants or result in distress to the occupants, or less than .5 psi/minute.

k) **Zipper Seal Test:** To demonstrate the true pressure boundary that of the outer jacket and web straps, an air-tight film bladder approximately the size of the interior of the PVHO will be inserted into the PVHO leaving all the zippers unzipped. The jacket will be closed and held together with just the hoop straps with flat shields across the zipper opening to keep the film bladder from bulging out. The PVHO will then be inflated to MAWP and held for 30 minutes without visible signs of air leaking or tearing.

### 4.2 Production Testing

a) All production units shall be subjected to a pneumatic test of 1.5 times the MAWP to be held for 60 minutes. In addition, airflow rate will be measured at MAWP over a 60 minute period.

b) Following testing, the PVHO shall be inspected for damage to the sealing areas. Every PVHO is to be examined visually and dimensionally. Any sign of cracks, permanent deformation, or other damage or airflow rate in excess of “normal” (see 4.1 (i) by more than 20% will be cause for review of the PVHO.

c) Any changes to production PVHOs built to this Case shall require prototype re-testing as defined in Para. 3.3 Design and Fabrication above.

### 5.0 QUALITY ASSURANCE PROGRAM

#### 5.1 General

The requirements of PVHO-1, Section 3, entitled The Quality Assurance Program (QAP) shall be complied with including specifically the following requirements and shall be reviewed and accepted by an independent third party inspection agency experienced in fabric composite design.

#### 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 non-conforming 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 process for design inputs and review
- A requirement for formal design review
- A process for product configuration management and change control

#### 5.4 Document Control

The QAP shall describe the manufacturer’s measures for assuring 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 assuring distribution of appropriate documents to the working areas in a timely fashion and the process for assuring non-use of obsolete documents.
5.5 **Procurement Control**
The QAP shall include the controls necessary to assure that applicable requirements are included in procurement documents. The manufactures shall describe the basis for source evaluation and selection and 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 personnel can easily determine quality status, material or item type, specification, lot of part as appropriate and job number. At least five (5) test samples of the key strength parameter shall be obtained from the lot of each pressure retaining material used in the Prototype testing-and each lot of material used for actual production. The upper value of the 90% Confidence Interval for the Production material shall be at least as great as the lower value of the 90% Confidence Interval for the material that were used in the Prototype units that were tested.

5.7 **Process Control**
The QAP shall include a Process Control Procedure that will record the identification of materials and items incorporate into the PVHO and each chronological step in its 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 carried out by appropriately trained and qualified personnel. Inspection points shall follow the activities in the process control plan. The integrity of heat seals shall be verified on each PVHO.

5.8 **Inspection Control**
The QAP shall include the measures used by the manufacturer to assure that inspections are reliable. These measures shall include:
   a) Proper qualification of inspection personnel
   b) Assurance that inspections are performed by person other than those performing or supervising work
   c) Documentation of all inspections
   d) Incorporation of acceptance criteria into inspection points in the Process Control Plan

5.9 **Test Control**
The QAP shall describe the measures used to assure 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) Tests 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 tests shall be performed by trained & qualified personnel.
   d) Tests shall be verified by persons other than those performing or supervising the test.

5.10 **Control of Measuring Test & Inspection Equipment**
The QAP shall describe the equipment used in inspections and tests and the measures used to assure 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 test equipment manufacturer’s recommendations shall be followed.

5.11 **Control of Non-Conforming 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 use. Nonconforming materials/items shall be identified and not used. The discrepant conditions(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:

Records shall be specified, compiled and maintained to furnish documentary evidence that services, materials and completed PVHO’s meet this and applicable referenced standards.

a) Records shall be legible, identifiable and retrievable
b) Records shall be protected against damage, deterioration or loss
c) Requirements and responsibilities for records transmittal, distribution, retention, maintenance and disposition shall be established and documented
d) Records shall be retained for a minimum of 12 years.

5.13 **Standard Repair Planning**

The QAP shall describe method for repairing discrepancies that may occur during the PVHO manufacture, such as heat-sealing burns not greater than 1” in diameter and skipped stitches. A complete list of discrepancies for which repair is permitted shall be prepared, along with their locations. All repair procedures shall be written and undergo testing equivalent to the requirements of prototype testing, to prove that the integrity of any repair does not compromise the integrity of the PVHO itself. Proof testing per 4.2 shall be conducted post repair. Full details of any repair will be noted in the device history file.

5.14 **Quality Assurance Overview by an Independent Third Party**

A qualified independent third-party individual or organization shall be employed to ensure that all PVHOs produced under this Case are designed, manufactured and tested to the requirements of PVHO-1 and this Case. This includes, but not restricted to the following:

a) The PVHO is designed in accordance with PVHO-1 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 Table 1 as required by PVHO-1 and this Case
d) The manufacturing operations are conducted in accordance with approved procedures by qualified operators as required by PVHO-1 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 and this Case
g) The PVHO is marked in accordance with PVHO-1 and this Case
h) A visual inspection of the PVHO is conducted to confirm that there is no material or dimensional defects

The manufacturer shall arrange and give the third party inspection individual or organization free access to all facilities associated with the manufacture of the PVHO. The manufacturer shall keep the third party inspection individual or organization 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.
6.0 Marking

a) In lieu of PVHO-1, Section 1-9, Marking, the external surface of the jacket shall be permanently marked with stencil, close to one end, with the data required in PVHO-1, Section 1 9.1, and the following (sample) designation:

8-27PVHO-1 2012 (case XX_)-HTI-0001-2011

Where

8 = MAWP, psig (.55 bar)
27 = inside diameter, in. (.69 m)
PVHO (Casexx) = PVHO designator and Case number
HTI = manufacturer’s initials
0001 = manufacturer’s unique identification for the PVHO
2011 = year of manufacturer

b) The jacket of the PVHO will be labeled to indicate:

- Maximum Allowable Working Pressure is 8 psig, 18 FSW, .55 BARG
- Operating temperature range (min/max 32°F/100°F)
- Storage temperature range (min/max -10°F/150°F)
- Allowable life is 4000 cycles
- Maximum allowable Airflow rate to maintain operating pressure is 15 SCFH (standard cubic feet of air per hour)
- Expiration date (10 years from date of manufacture)

DO NOT EXPOSE PVHO TO DIRECT SUNLIGHT OR UV LIGHT SOURCES FOR EXTENDED PERIODS

Maximum allowable folding cycles is 4000

c) The following restriction shall be conspicuously marked at the inlet port, “PRESSURIZE WITH AIR ONLY”.

d) Not for Hospital Use, Health Care Facilities, including nursing homes, limited care facilities, clinics, etc. (marked on PVHO)

e) Not suitable for decompression sickness treatment-. (marked on PVHO)

f) The following warning will be conspicuously marked ATTENDANT REQUIRED AT ALL TIMES

g) The following warning will be conspicuously marked DO NOT BRING PROHIBITIVE ITEMS THAT HAVE BEEN CLASSIFIED AS DANGEROUS INSIDE CHAMBER SUCH AS HAND-WARMERS AND ELECTRONIC DEVICES.

h) Chamber shall only be operated by qualified personnel.

7.0 Documentation

Form GR-1 in PV1-10-1 Section 1-7-9, shall be replaced with Form PVHO Case. Manufacture’s Date Report for Pressure Vessels for Human Occupancy, below. All other documentation requirements of Section 1-7.9 Section 5-1.3 shall be complied with.

Definition of “Lot” for fabricator’s testing requirements and traceability is the amount of homogeneous run of material made at the same time in a pre-determined quantity (i.e. yards or pounds) and the specific quantity received from such a lot. Each “lot” shall as far as practicable, consist of units of product of a single type, grade, class, size, and composition, manufactured under essentially the same conditions, and at essentially the same time.
FORM PVHO CASE MANUFACTURES’S DATA REPORT FOR PRESSURE VESSELS FOR HUMAN OCCUPANCY

1. Manufactured and Certified by __________________________________________

2. Manufactured for _______________________________________________________

3. Vessel Identification ____________________________________________________
   (Mfr. Serial no.) (Year Built)

4. The design, construction, workmanship, and chemical and physical properties of all parts meet the applicable material specifications of PVHO-1 2012 Edition and Case Nos. The ultimate strength of the webbing is __________, the jacket is __________, the buckle is, __________, the bladder is ________________, the penetrator flange is ________ and the film is __________.

5) Window Shield: Certification Reports, properly identified and signed by the window fabricator are attached for the acrylic material.

6) Manufactured for a maximum allowable working pressure of 8 psig, a maximum working temperature of 100°F and a pneumatic test pressure of 12 psig. Ten year life ending.

7) Design analysis conducted by ____________________________________________

8) Service life limitations: 10 years from date of manufacture, 4,000 pressure cycles, 4,000 folding cycles, whichever occurs first.

CERTIFICATION OF DESIGN, FABRICATION & QUALITY ASSURANCE

User’s Design Specification on file at _______________________________________
Manufacturer’s Design Report on file at _________________________________
Prototype test program attested by _________________________________

Quality Assurance Program reviewed by ________________________________
Fabrication documentation reviewed by ________________________________

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 of this vessel conform to the A SM E Safety Standard for Pressure Vessels for 1 Human Occupancy (PVHO-1) 2012 Edition and PVHO Case

Date______ Company Name _____________________ Signed ________________