U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, SE
Washington, D.C. 20590

MAY 2 3 2013

Mr. Edward Petrullo
Director, EH&S
Curtis Bay Energy
3200 Hawkins Point Road
Baltimore, MD 21226

Reference No. 12-0247

Dear Mr. Petrullo:

This is in response to your October 25 and 26, 2012 e-mails; October 22, 2012 telephone call with a member of my staff; and October 23, 2012 conference telephone call with employees of Curtis Bay Energy and a member of my staff. You ask if two different United Nations (UN) 4H2 red polyethylene containers with polyethylene lids designed to transport a "UN 3291, Regulated medical waste, n.o.s., 6.2 (Category B infectious), Packing Group (PG) II," (RMW) including sharps, comply with the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) when transported in different packaging configurations. We summarized the descriptions you provided for each packaging and paraphrased and answered your questions below.

Packaging 1: UN 4H2 with Sliding Lid

You enclosed a test report prepared by Container-Quinn Testing Laboratories, Inc., for Rotonics Manufacturing, Inc., that describes the first packaging as a 17-gallon oblong, trapezoid-shaped, red-polyethylene container with handles, and with extended edges on both longitudinal sides on the top of the packaging that would permit it to be suspended from the side rails of an appropriately sized wheeled-metal rack. The test report also states the polyethylene lid on this packaging slides and locks, is securely closed with a 1/8th-inch wide reinforced polyethylene cable tie, and that the packaging can be stacked. In addition, the test report states this container's inner packagings consist of RMW contents placed inside one 3-ml red polyethylene bag with a bottom seam that is heat-sealed and a top that is twisted and knotted tightly closed. This bag is then placed inside of another identical polyethylene bag that is also closed in the same manner. The test report describes the inner packaging's test contents as consisting of a one-gallon sharps container, one gallon of water in four one-quart glass jars, miscellaneous polyethylene test tubes, rags, paper and cloth towels, empty glass jars, polyethylene trays, corrugated paper, and paper dunnage that together weigh a total of 21.3 pounds. The test report further states the gross weight of the completed package is 28.4 pounds (12.9 kg) and the package is marked "UN 4H2/Y 12.9/S/**/USA/CQ12160," but does not include drawings or a photograph of the packaging. You provided photographs of these packagings, both empty and filled.

Packaging 2: UN 4H2 with Hinged Lid

You enclosed a test report prepared by Gaynes Labs, Inc., for the Rehrig Pacific Company that describes the second packaging as a 17-gallon oblong, trapezoid-shaped, red-polyethylene container with two integral handles and extended edges on both longitudinal sides on the top of the packaging that would permit it to be suspended from the side rails of an appropriately sized medical waste transport rack. The test report also states that the packaging has a rectangular polyethylene (main) lid attached to its base by a continuous hinge located on one long side at the top of the packaging, a second inner (sub) lid attached to the main lid by three hinges and one latch, and that the packaging can be stacked. In addition, the test report describes the test contents for this packaging as consisting of a solid mixture of sand and vermiculite placed directly inside each packaging without any liner to a maximum fill capacity of 95% and a gross weight of 22.6 kg. The test report includes two drawings of the packaging and states it is marked "UN 4H2/Y 22.6/S/11/USA/+AB2091." You did not provide a photograph of this packaging.

Questions

Q1. Do both packagings comply with the HMR when transporting RMW: 1) on the floor of a truck as an individual packaging; 2) inside of a fiberboard box; 3) strapped or shrink-wrapped to a pallet; or 4) suspended in rows from a wheeled-metal rack?

A1. A polyethylene box that meets the requirements in the HMR for a UN 4H2 packaging at the PG II performance level is an authorized hazardous materials packaging. Provided it complies with all applicable requirements of the HMR, including being prepared and closed for transportation in the manner described in the manufacturer's closure instructions, a completed authorized package containing RMW may be transported:

- As a single package;
- On the floor of a truck if properly secured and blocked against shifting, including motion between packages (see § 177.834(a)); and
- Inside an overpack, as defined in § 171.8, such as inside a fiberboard box, strapped or shrink-wrapped to a pallet, or properly enclosed and suspended from the side rails of a wheeled-metal rack.

However, please note to demonstrate the packaging's puncture resistance for sharps and sharps with residual fluids, § 173.197(b) requires that before they are performance tested non-bulk RMW packagings used as sharps containers must be filled with materials representative of the sharps and fluids (such as sterile sharps) intended to be transported in the packagings. Section 178.602(c) also states:

> If the material to be transported is replaced for test purposes by a non-hazardous material, the material used must be of the same or higher specific gravity as the material to be carried, and its other physical properties (grain, size, viscosity) which might influence the results of the required tests must correspond as closely as possible to those of the hazardous material to be transported. Water may also be

used for the liquid drop test under the conditions specified in § 178.603(e) and additives, such as bags of lead shot, to achieve the requisite total package mass, so long as they are placed so that the test results are not affected. See §§ 173.197(b) and 178.602(b) and (c).

Based on the test report prepared by The Rehrig Pacific Company, the UN 4H2 packaging with the hinged lid (Packaging 2) passed the tests at the PG II performance level to transport materials with the same physical characteristics present in a solid sand-vermiculite mixture but has not passed tests authorizing it to transport sharps, as this term is defined in § 173.134(a)(6), and liquids, as this term is defined in § 171.8. In addition, the HMR permits sharps to be transported in non-bulk, non-specification sharps packagings that meet the general packaging requirements in 49 CFR 173.24 and 173.24a, and the U.S. Department of Labor's bloodborne pathogen requirements in 29 CFR 1910.1030 when transported by only private or contract carrier. See § 173.134(c)(1)(ii).

Because the packaging you described is an authorized UN standard packaging, it may also be placed inside of an overpack. An overpack is a container or enclosure used by a single consignor to provide protection or convenience in handling or to consolidate two or more packages (see § 171.8). Examples of an overpack include packages: 1) placed or stacked on a pallet that are secured to it by strapping, shrink wrapping, stretch wrapping, or other suitable means; or 2) placed in a protective outer packaging, such as a box, crate, or wheeled-metal rack. For a completed authorized package of hazardous material to be placed in an overpack, it must comply with the requirements prescribed in § 173.25, which include the following:

- Forbidden hazardous materials and packages, as prescribed in § 173.21, are not permitted;
- The authorized package must comply with general packaging requirements prescribed in § 173.24;
- When applicable, required marks and labels representing each of the hazardous materials contained in an authorized package must be visible when one or more of these packages is placed in an overpack, if they are not, this information must be repeated on the outside of the overpack; and
- When packagings placed inside of the overpack are required to be Department of Transportation (DOT) specification or UN standard packagings and the marks that specify the package's design type are not visible, the word "OVERPACK" must be marked on the outside of the overpack.

Q2. Must we use a wheeled cart if our 17-gallon reusable container is not gasketed?

A2. No. Based on the information you provided, both packagings satisfied the HMR's performance tests without the use of gaskets; therefore, placing them in a wheeled cart or a wheeled-metal rack is not required. However, a wheeled cart or wheeled-metal rack may be used as an overpack as described in Answer A1.

Q3. Is a gasket required on a packaging for it to be "leak proof"?

A3. No. A packaging is considered leakproof under the HMR if it satisfies the leakproofness test prescribed in § 178.604. However, please note inner packagings of combination packagings are not subject to the leakproofness test requirements of § 178.604 (see § 178.604(a)(2)).

Q4. Are we allowed to use "secondary containment" for our 10- and 17-gallon containers if we do not use a wheeled cart?

A4. Yes, see Answer A1.

Q5. Can a container that has a third-party testing lab performance-orientated package testing certification stand on the floor of a trailer or truck without a cart?

A5. Yes, provided it is properly blocked and braced. See Answer A1.

Q6. The Rotonics 17-gallon (Packaging 1) container was tested using two inner red bags. Please advise what our transportation options are for this packaging under the HMR if we add additional red bags to the container, and what they are if we remove the red bags.

A6. Any change in structural design (such as the addition or removal of packaging components), size, material of construction, wall thickness, or manner of construction to a UN 4H2 packaging constitutes a different packaging under the HMR that is subject to design qualification testing (see § 178.601(c)(4)). However, the HMR permits selective testing of non-bulk packagings that differ in only minor respects from tested designs as specified in § 178.601(g).

Q7. Is use of a wheeled cart or rack required to have a Special Permit if we transport reusable sharps containers?

A7. If a hazardous materials packaging is authorized as acceptable in transportation under the HMR, it may be transported using a consolidation device like a wheeled cart or rack without having to operate under the terms of a Special Permit. An unauthorized packaging that contains a hazardous material must not be offered for or entered into transportation in commerce without a competent authority approval in the form of a written Special Permit or Approval, as these terms are defined in § 107.1, that is issued by the Competent Authority of the United States, the Associate Administrator of Hazardous Materials Safety. The procedures for applying for a Special Permit or to become a party to an existing Special Permit are found in 49 CFR Part 107, Subpart B. The procedures for applying for an Approval are found in 49 CFR Part 107, Subpart H. For a more detailed explanation of this application process, see Answer A9.

Q8. You state the owner of Solutions, Inc., told your company through a distribution agreement that your company may use his wheeled racks and containers without separately applying

for a Special Permit and ask if this statement is true? You state his Special Permit number is DOT-SP 13556.

A8. The use of a Special Permit may not be authorized through a private company's distribution agreement. As stated in Answer A1, an authorized hazardous materials packaging may be placed inside of an unauthorized packaging, like a wheeled rack, that is used as an overpack without having to apply for specific relief from the HMR under the terms of a Special Permit or Competent Authority Approval. An unauthorized packaging must not be used to transport a hazardous material in commerce without the specific authorization of the Associate Administrator of the Office of Hazardous Materials Safety.

Q9. You also ask what your company would need to do to apply for a Special Permit if it were to design its own wheeled cart?

A9. To initate a request for a new Special Permit, your company may wish to submit an application to the Associate Administrator for Hazardous Materials Safety that conforms with the requirements prescribed in 49 CFR Part 107, Subpart B. The application must contain sufficient information to demonstrate that, if a Special Permit is issued, the method of relief requested achieves a level of safety that is equal to or greater than that required under the HMR. You may also obtain this information from our website at http://www.phmsa.dot.gov/hazmat/regs/sp-a.

Packages authorized under a Pipeline and Hazardous Materials Safety Administration (PHMSA) Special Permit (DOT-SP) do not otherwise comply with the HMR, and must be examined and approved for use by PHMSA's Associate Administrator for Hazardous Materials Safety. If your company chooses to apply for a Special Permit, it must include in its application sufficient information about the packaging's design and performance to prove the packaging meets or exceeds the requirements prescribed in the HMR for the hazardous material intended for the packaging. Also, to learn who may use a packaging authorized under existing Special Permit DOT-SP 13556, please contact the Approvals and Permits Division at either (202) 366-4535 or (202) 366-4511.

I hope this satisfies your request.

Sincerely,

T. Glenn Foster

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Edmonson
§173.197
§173.134
§173.24
§173.24a
Regulated Medical Waste
12-0247

Drakeford, Carolyn (PHMSA)

From: Edmonson, Eileen (PHMSA)
Sent: Friday, October 26, 2012 6:20 PM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: 911------ Fwd: Special Permit
Attachments: How to UNZIP.html; SecureZIP Attachments.zip

Carolyn –

Please log this e-mail in and assign it to me for response. The sections discussed by order of importance are:

§§ 173.197(b),
178.602(b) and (c),
173.134(a)(6),
173.24,
173.24a,
107.107,
and
171.16.

I also have 2 test reports to include with the original.

Thanks,

Eileen Edmonson
USDOT/PHMSA
(202) 366-4481 (w)
(202) 366-7041 (f)
eileen.edmonson@dot.gov (e-mail)
http://www.phmsa.dot.gov/hazmat (website)
infocntr@dot.gov (Hazmat Info Center E-mail)

From: Edward Petrullo [mailto:epetrullo@curtisbayenergy.com]
Sent: Thursday, October 25, 2012 12:02 PM
To: Edmonson, Eileen (PHMSA)
Subject: Re: 911------ Fwd: Special Permit

I will try again but it does show up on my computer and e-mail. Basically their container is 17 gallon with no testing using any red bags and is approved. They did use 50 pounds of wet sand and vermiculite and no "sharps" or materials one would argue maybe they should. Can you address the dialog and questions from Debbie. What does the country now do that use 17 gallon rotonics? Solutions stated today their wheeled carts and containers they distribute can be usedaccording to thier interactions with DOT through the purchase and distribution agreements. In other words, we are users of the special permit. We do not need to separately go get one. But the special permit is not a regualtion and we do not have to follow it if we care to place 17 gallon containers in secondary containers, shrink wrap on a pallet, or place on the floor. Thoughts?
On Thu, Oct 25, 2012 at 10:07 AM, <eileen.edmonson@dot.gov> wrote:
Ed – The adobe acrobat file would not open because it is damaged. Can you check it and send it again?

Eileen Edmonson
USDOT/PHMSA
(202) 366-4481 (w)
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http://www.phmsa.dot.gov/hazmat (website)

infocntr@dot.gov (Hazmat Info Center E-mail)

From: Edward Petrullo [mailto:epetrullo@curtisbayenergy.com]
Sent: Thursday, October 25, 2012 9:00 AM
To: Edmonson, Eileen (PHMSA)
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Dear Eileen,
Please read the below reaction by our satellite office. I can tell you that these folks are not very knowledgeable on regs in general and the terminology confuses them. You can see the "sky is falling" reaction. Can you send on a clean e-mail answers to the points Debbie writes. They have already had it explained that the Stericycle's special permit (others have applied to be users) was relief for using a non-leak proof BOP - the wheeled cart. Tracy only being with Stericycle in this industry has convinced Debbie that special permit is a regulation and everyone using reusable sharps containers must comply. I think we confused folks the other day by first saying "secondary containment" is one remedy that most of the industry uses and then later you said we had to test any out package we used for the 17 gallon. If 2 liners and needed and those 17 gallon containers cannot sit on the floor of a truck, 95% of the medical waste haulers in the country are out of compliance and the industry could freak out. I believe you can address whether the 17 gallon container can have a red bag or two put on its outer package (if they are resistant to placing 2 bags inside the container as I have tried to suggest as a remedy). I also think we can place these containers in a box and bag, or a 96 gallon tote, or a 200 gallon tote, or how about on a pallet and shrink wrap for transport four high and five across (for example).

I can tell you that our new management needs to clearly have something of a remedy in writing and Debbie will continue to argu things like 3 mil lines can leak. These liners must be ASTM certified passing the dart and tear tests. Rarily is there amy liquids in containers and more rarily do red bags break at the 3 1 thickness. We have no historu of spills or containers falling over. We have been transporting 300 of these 17's on a truck floor bi-weekly for years. Can you please help us to simply have a way to proceed without all the maybe's. The Snyder Corp should be reprimanded perhaps for their testing process and then not having a matching closure doc. It says no sharps in that doc as well confusing the consumers. I am adding a new container just FDA approved that is tested for 50 pounds and without red bags inside. This Rehrig-Pacific 17 and 10 gallon can sit on the floor withour a wheeled cart. see attached and please let me have in writing something this week.

Are there any interpretations on wood floors in trailers or medical waste box trucks?
Thanks.

On Wednesday, October 24, 2012, Debbie Schlarb <dschlarb@curtisbayenergy.com> wrote:
> Good Morning,
>
> Per our conference call yesterday, are we to understand that we are out of compliance with the special permit since we do not have it under Curtis Bay Energy's name? If this is so, are we transporting sharps containers illegally?
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> 1. When Ed stated to Eileen that Victor from Solutions said we can use "his" Special Permit, her response was "is solutions a parent company to CBE?" So my question is..can we use Victor's Special Permit in our trucks that haul the reusable sharps, because no answer was given.
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Curtis Bay Energy
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F: 800-699-0972
http://www.curtisbayenergy.com

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Director, EH&S
Curtis Bay Energy
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Cell: 602-625-5002
Curtis Bay Energy
3200 Hawkins Point Road

Baltimore, Maryland 21226
F: 800-699-0972
http://www.curtisbayenergy.com

Report No.: 12160
Re: SDC 17Gal 13" Opening Red with Transport Lid

Date of Report: 3/21/11
Date of Revision: dna

CONTAINER-QUINN TESTING LABORATORIES, INC.

A division of H.H. Holmes Testing Laboratories, Inc.
170 Shepard Avenue, Wheeling, IL 60090
Phone: 847-537-9470 Fax: 847-537-9098
E-Mail: spowell@container-quinn.com

3rd PARTY TESTING LABORATORY
PERFORMANCE ORIENTED PACKAGE TESTING CERTIFICATION

Performed by:
Container-Quinn Testing Laboratories, Inc.
170 Shepard Avenue
Wheeling, IL 60090

Testing Performed for:
Rotonics Manufacturing, Inc.
Attn.: Susan B. Hornat
736 Birginal Drive
Bensonville, IL 60106
630-773-9510

Design Qualification Testing for a
UN 4H2 17-gallon oblong openhead Plastic container with sliding transport cover containing two (2) 3-mil polyetylene red bags (one inside the other)

u
n

4H2 / Y 12.9 / S / **
USA / CQ12160

** is to be replaced by the year of box manufacturer

Certification Expires: 3/21/13

CONTAINER-QUINN TESTING LABORATORIES, INC.

APPROVED BY:

Stephen C. Powell - Laboratory Director

Section 1

Box: See Appendix A for Drawing and/or Picture(s)

Manufacturer:	Rotonics Manufacturing, Inc., Bensonville, IL
Box Description:	17-gallon, oblong, poly unit with handles and slidetop transport top with 1/8" wide reinforced plastic cable tie closures
Material:	LLDPE
Part Number:	SDC 17GAL
Outer Dimensions:	18 1/4" x 13 1/4" x 25"
Tare Weight:	6.9 lbs. with transport lid 6.1 lbs. alone
Description:	17-gallon, tapered to nest and stack, with sliding and locking transportation lid

Inner Bag: See Appendix A for Drawing and/or Picture(s)

Manufacturer:	Solutions, Inc., KY
Mfg. Method:	Blowmolded
Part Number:	misc.
Material:	LLDPE
Sidewall Thickness:	3-mil
Bag Information:	3-mil Red Bag with heat sealed bottom seal, twisted and knotted tightly.
Quantity:	2 - one inside the other and sealed together

Additional Test Information

Overall Weight of Package:	28.4 lbs. (12.9 kg)
Overall Tare Weight of Package:	7.1 lbs
Test Contents:	Poly red bag containing one (1) 1-gallon oblong sharps containers, 1-gallon water in (4) 1-quart glass jars, misc plastic test tubes along with misc. rags, paper and cloth towels, empty glass jars, plastic trays, corrugated and paper dunnage to equal 21.3 lbs.
Authorized Package Gross Wgt:	28.4 lbs. (12.9 kg)

Closing Methods:

Plastic Tote Shipper:

Sealing Method:	(2) 1/8" wide reinforced plastic cable tie closures snuggly secured

Section 2

Test Descriptions and Results

Package Preparation - For All Testing
The packages were filled to capacity with miscellaneous dunnage fill materials

DROP TEST

Test Method: 49CFR 178.603
Test Packages: 5
Drop Height: 1.2 meters (47.25") (Calculation for drop height is provided in Appendix B)
Equipment: Split Table Drop Tester

Testing was conducted to certify the package for PGII

Conditioning:
The packages were conditioned to -18+/-3° C and Ambient RH, in accordance with 49CFR 178.603(c). The packages were conditioned for 48 hours to ensure the package and contents were at the proper temperature prior to testing. Drop testing was conducted approximately 5-minutes after removal of the test package from the conditioning chamber.

Results

Box Number	Package Weight	Orientation	Results
1	28.4 lbs.	Bottom, Mfg. Corner	Pass - no damage
2	28.4 lbs.	Flat on short side	Pass - no damage
3	28.4 lbs.	Flat on long side	Pass - no damage
4	28.4 lbs.	Flat on top	Pass - no damage
5	28.4 lbs.	Flat on bottom	Pass - no damage no release of the inner packages from the outer package, no leakage of the filling substance from the bottles noted

Pass/Fail Criteria -
A package is considered to successfully pass the drop tests if for each sample tested: There is no damage to the outer packaging likely to adversely affect safety during transport, there is no leakage of the filling substance from the inner packaging and any discharge from a closure is slight and ceases immediately after impact.

Special Note:
After each drop test, test product was removed from test polybag. 2-gallons water was placed in the polybags and polybags were laid on first one side and then the other for 15-minutes each. No leakage was noted. Dual polybags retained water. Polybags were then reincerted in container, lid placed in closed position and container was inverted for 2-hours with no leakage

STACKING TEST

Test Method:	49CFR 178.606
# Test Packages:	3
Method:	Free Standing
Test Duration:	24-hours

Conditioning:
The packages were conditioned to 23+/-3° C and 50+/-5% RH, in accordance with 49CFR 178.602(d).

Stack Weight (lbs): 110 (See Appendix B for calculation)

The stacking test load was applied to the top of the packages by loading each package with the calculated weight and maintaining that weight for a minimum of 24-hours.

Results:

1	Passed	No damage to the packaging, normal and expected packaging fatigue and crush
2	Passed	No damage to the packaging, normal and expected packaging fatigue and crush
3	Passed	No damage to the packaging, normal and expected packaging fatigue and crush

Pass/Fail Criteria -
No test sample may leak. There must be no leakage of the filling substance from the inner receptacle or inner packaging. No test sample may show any deterioration which could adversely affect transportation safety or any distortion likely to reduce its strength, cause instability in stacks of packages, or cause damage to inner packagings likely to reduce safety in transportation.

REPETITIVE SHOCK VIBRATION TEST

Test Method:	49CFR 178.608
# Test Packages:	3 one same table
Method:	Repetitive Shock
Test Duration:	1-hours
Frequency:	4.0 Hz (239 cpm)
Equipment:	Lansmont Vibration Table
Displacement:	1"

Conditioning:
The packages were conditioned to 23+/-3° C and 50+/-5% RH, in accordance with 49CFR 178.602(d).

Results:

1	Passed	No damage to the packaging, normal and expected packaging fatigue and crush
2	Passed	No damage to the packaging, normal and expected packaging fatigue and crush
3	Passed	No damage to the packaging, normal and expected packaging fatigue and crush

Pass/Fail Criteria -
No test sample may leak. There must be no rupture or leakage of the filling substance from any packages. No test sample may show any deterioration which could adversely affect transportation safely or any distortion likely to reduce packaging strength

Appendix A
Drawings and/0r Pictures of Packaging Components

See attached photos, drawings and specification sheets

Appendix B
Calculations

1. Weight of test package:

Total Gross Weight of Sample: 28.4 lbs. (12.9 kg)

2. Drop Test Height

Package Group of Certification		
Drop Height for PG II	1.2 meters	
Specific Gravity	dna	
Calculation for PG II	SG x 1.2	
Drop Height for PG II		
(1.2 x 1.0)	1.2	meters
(1.2 x 3.2808' x 12)	47.244	inches

3. Stack Test Weight

Load = (118.11 - h) /h * w

Where: 118.11 = height of stack test (3 meters)
h = height of package as tested and sealed
w = weight of tested package (lbs.)

Package Height:	25"
Weight of Package:	28.4 lbs.
(118.11-25)/25	3.724400
3.7 x 28.4	105.8
Test Weight:	110

Appendix C
Test Equipment and Instrumentation

Instrument/Equipment	Manufacturer	Model Number
Split Table Drop Tester	LAB	
Hydrolic Vibration Tester	Lanamont	1500S
Weight Scale, large	GSE	GSE 500
Weight Scale, small	GSE	