The following questions and answers were developed as a result of agenda items discussed at the June 2000 Performance-Oriented Packaging Meeting in Chicago:

1) § 171.8: If a packaging consists of an outer fiberboard box with an inner plastic bladder bag that may be emptied either through an opening in the packaging or by removing the bag, hanging it on a hook, and dispensing the liquid contents, is it a composite (UN 6HG2) or a combination (UN 4G) packaging?

A composite packaging is a packaging consisting of an outer packaging and an inner receptacle constructed so that the inner receptacle and the outer packaging form one integral packaging. Once assembled, a composite packaging remains an integrated, single unit – it is filled, stored, shipped, and emptied as a single unit. By contrast, a combination packaging consists of one or more inner packagings secured in a non-bulk outer packaging. The inner packaging of a combination packaging is intended to be removed from the outer packaging for emptying. The inner receptacle for the packaging described in the question above can be used as either an integral component of the packaging or a separate inner packaging of a combination packaging. We consider such a packaging to be a combination packaging because the inner packaging may be removed for emptying. A composite packaging must be filled and emptied as a single unit.

2) § 173.24: What are the characteristics of a "strong outer packaging" for consumer commodities?

The term "outer packaging" is defined in § 171.8; however "strong outer packaging" is not. Generally a strong outer packaging is a packaging that is sturdy, firm, and durable, constructed so that it will retain its contents under normal conditions of transportation, including rough handling. In addition, a strong outer packaging must conform to all other applicable requirements of § 173.24. The exact characteristics of a strong outer packaging depend primarily on the type of hazardous materials that will be shipped in the packaging and the capability of the packaging to contain the material without leakage under normal transportation conditions.

3) § 173.27: What is an acceptable test method for applying the internal pressure capability standard to a plastic bag?

A vacuum test is not suitable for determining if a flexible inner packaging is capable of meeting the pressure differential requirements in § 173.27(c) or ICAO TI 3;1.1.1.6.

The following test may be used to determine if a flexible packaging is capable of meeting pressure differential requirements:

1. Replace vented closures with similar non-vented closures or seal the vent.

2. Restrain the packaging under water while applying internal pressure. The method of restraint must not affect the test results.

3. Pressurize the packaging until a pressure differential equivalent to the greater of the pressures specified in paragraphs (i) or (ii) is achieved.

   (i) An internal pressure that produces a gauge pressure of not less than 75kPa (11 psi) for liquids in Packing Group III of Class 3 or Division 6.1 and 95 kPa (14 psi) for all other liquids; or

   (ii) A pressure related to the vapor pressure of the liquid to be transported, as determined by one of the following:

   – The total gauge pressure measured in the receptacle (i.e., the vapor pressure of the material and the partial pressure of air or other inert gases, less 100 kPa (15 psi) at 55EC (131EF) multiplied by a safety factor of 1.5; determined on the basis of a filling temperature of 15EC (59EF) and a degree of filling such that the receptacle is not completely liquid full at a temperature of 55EC (131EF) or less;

   – 1.75 times the vapor pressure at 50EC (122EF) less 100 kPa (15psi); or

   – 1.5 times the vapor pressure at 55EC (131EF) less 100 kPa (15 psi).

4. Maintain the pressure differential for at least 30 minutes. The pressure differential must be applied continuously and evenly, and it must be kept constant throughout the test period.

5. While it is pressurized, observe the packaging for signs of leakage, such as a continuous stream of recurring bubbles coming from the packaging. Isolated bubbles caused by trapped air are not evidence of leakage.

6. A package passes the pressure differential test if, for each test sample, there is no leakage from the packaging.

4) § 173.134: Must packaging used in conformance with the packaging exception for regulated medical waste, including sharps, in § 173.134(b)(3)(ii) be puncture resistant?

Yes. The packaging for regulated medical waste authorized under § 173.134(b)(3)(ii) must conform to the general packaging requirements specified in §§ 173.24 and 173.24a and OSHA requirements in 29 CFR 1910.1030. Under § 173.24, the packaging must be designed, constructed, filled and closed so that there will be no release of the hazardous material under normal conditions of transportation. The OSHA regulations require containers for contaminated sharps to be puncture resistant and leakproof on the sides and bottom.

5) § 173.197: This section requires regulated medical waste packaging to be leak resistant and puncture resistant. Who is responsible for making this determination? What testing procedures or criteria should be used for making this determination?

A packaging authorized for the transportation of regulated medical waste must pass the performance tests specified in Part 178 at the Packing Group II performance level. In addition, the packaging must conform to the requirements specified in paragraphs (a) through (g) of § 173.197; however, the regulations do not specify tests for determining if a packaging conforms to the requirements of paragraphs (a) through (g). The shipper is responsible for assuring that the packaging selected for transporting regulated medical waste conforms to the paragraph (a) through (g) requirements. This determination may be made through testing or other means. For example, we would encourage shippers and testing laboratories to determine a packaging's puncture resistance based on tests with a non-hazardous material that corresponds as closely as possible to the hazardous material to be transported. In this case, clean sharps and residual fluid would be appropriate. The packaging test report or other documentation should indicate how leak resistance and puncture resistance were determined.

6) § 173.465: When testing a Type A packaging for radioactive materials that are liquids or gases, must the water spray test in § 173.465(b) be performed prior to the 9m free drop in § 173.466(a)(1) and the penetration test in § 173.466(a)(2)?

All Type A packaging tests originate in the International Atomic Energy Agency's (IAEA) Regulations for the Safe Transport of Radioactive Material, 1996 Edition (ST-1). IAEA states in their advisory material that the additional tests for a Type A package designed to contain liquids or gases are imposed because liquid or gaseous radioactive material has a greater possibility of leakage

than solid material. The tests need not be performed in any particular order.

7) § 178.503: May a packaging manufactured and marked in China, which is being used in the U.S. to ship hazardous materials, be tested by a third-party lab in the U.S. and marked with a "+" designation?

A packaging manufactured in a foreign country may be tested by a U.S. third-party test lab. If the foreign country's competent authority approves the use of a U.S. third-party lab symbol the packaging may be marked with the "+" designation.

8) § 178.503: If a component of a packaging (e.g., an inner bottle) was manufactured outside of the U.S., may the packaging be marked "USA?"

The "USA" mark may only be applied to a packaging that was manufactured in the U.S.. A packaging that was assembled, tested and marked in the U.S. could be considered to have been manufactured in the U.S. and marked "USA," even if one or more of the components were manufactured outside of the U.S..

9) § 178.503: Is there a capacity for a metal drum below which specification marking information need not be embossed? For example, a 12-gallon drum has its specification marking information on a label applied to the drum. Is this acceptable?

A reusable metal drum liable to undergo a reconditioning process must bear the marks identified in 178.503(a)(1) through (a)(6) and (a)(9)(i) to be in a permanent form which is able to withstand the reconditioning process. Although it may be possible to permanently apply these marks in some other fashion (e.g. , stamping or etching), embossing is the most common method of permanently marking steel drums. A label generally would not insure permanency.

For a new metal drum with a capacity greater than 100 L the permanent marks described in § 178.503(a)(1) through (a)(6) and (a)(9)(i), must appear on the bottom. Other required marks need not be permanent and may appear as part of a complete marking on the side or top of the drum. Again, a label generally would not insure permanency. If the capacity of the drum is less than or equal to 100 L the markings may be anywhere on the drum.

10) § 178.503: Who is the "manufacturer" of a combination packaging where Company A produces the inner receptacles, Company B makes the fiberboard box and Company C sends it to a third party for testing and certification?

The "manufacturer" is the person whose name or symbol is marked on the packaging, or identified through the mark of a third-party lab, to certify that appropriate testing has been performed and the packaging design is capable of passing the performance tests.

11) § 178.503: A manufacturer has a packaging tested by a third-party lab. She chooses to use a different lab when the time comes for the periodic design requalification. May she continue to use the marking of the original third-party lab on any packaging manufactured after the design requalification?

Yes. If a packaging does not differ from its original design certification, the HMR permit the packaging to continue to be marked with the name or symbol of the third-party lab that certified the initial design. For consistency with international requirements, because other countries do not have requirements for periodic packaging design requalification, the original mark may remain on a packaging for as long as it is produced. Permitting continued use of the original marking also saves manufacturers the cost of third-party lab recertification and/or the cost of remarking packagings. The ability of a manufacturer to use the original third-party lab mark may be limited by contractual arrangements. However, so long as the packaging is not changed and there is no misrepresentation of the original certifier, it is not a violation of the HMR to retain the original marks on a packaging. This is why it is so important for the original certifier of a packaging to be able to accurately identify the packaging it tested and to document the tests performed.

The HMR permit periodic packaging recertifications to be performed by the original third-party lab, a different lab, or the packaging manufacturer. The manufacturer has the option of leaving the original mark on the packaging, using its own mark or, if a different designated lab is used, marking it for the lab performing the recertification. The recertification report must be maintained at each location where the packaging is manufactured; there should be no difficulty locating the report.

12) § 178.601: If a company buys a five-year supply of materials used to manufacture a UN packaging, is it allowed to use the inventory until it runs out, however long that may be? It is possible for corrugated materials to lose strength in the warehouse

or for plastics to become brittle. Is there a time limit imposed on existing inventory of materials of construction?

Nothing in the HMR places a time constraint on the length of time during which a packaging may be manufactured. However, as provided by § 173.24(b), each packaging used for the shipment of hazardous materials must be, among other things, constructed and maintained so that the effectiveness of the packaging will not be substantially reduced. In addition, as provided in § 178.601(b) it is the responsibility of the packaging manufacturer to ensure that each packaging is capable of passing the prescribed test. Further, if the characteristics of materials of construction change over time, the packaging would be a different packaging as defined in § 178.601(c)(4) and require retesting.

13) § 178.601: A client sends in a packaging with printing on the carton for certification testing and the packaging passes all required tests except for the Cobb test. The client sends in the same carton, only without the print on it, and it passes all the tests, including the Cobb test. When must the Cobb test be performed? Should the Cobb test be performed on fiberboard that is already printed?

A. The Cobb test is not part of Part 178, Subpart M testing requirements. This test may be performed by the board manufacturer. If the unformed fiberboard meets the Cobb test, the packaging requirements are satisfied. We advise test labs to perform the test on numerous samples including those with and without surface treatments such as ink.

14) § 178.601: Should a packaging, where the surface treatment has an affect on the packaging, be considered a different packaging if the surface treatment is substituted, altered, or not applied? For example, a water repellant treatment is added as a surface treatment to a box so the packaging can pass the Cobb test. The surface treatment is subsequently switched and the packaging still passes the Cobb, but with differing results. Is this still an identical packaging?

The Cobb test required by § 178.516 applies to the base material, not the finished packaging. A packaging that differs only in surface treatment is not considered to be a different packaging.

15) § 178.601: What is the minimum information that must be provided in the test report for a UN packaging?

RSPA has not specified the level of detail that a test report must contain. However, the test report must be sufficiently detailed so that the test can be reproduced, and the tested design type can be specifically identified through reference to the test report. Sufficient information must be provided to ensure there is no change to the structural design, size, material of construction, wall thickness, or manner of construction as provided by § 178.601(c)(4) and every packaging meets the design standard. RSPA encourages packaging manufacturers and testers to develop uniform guidelines for information contained in test reports.

17) § 178.601: Why doesn't RSPA amend the HMR to allow box manufacturers and users to change liners and dividers in corrugated boxes, without the need for retesting the packaging?

As set forth in § 178.601(c)(4), a change in structural design, size, material of construction, wall thickness, or manner of construction is a different packaging. The only variances allowed are those set forth in § 178.601(c)(4)(i) through (vi) and § 178.601(g). We have encouraged industry associations to further refine design type definitions, as has been done for steel drums in § 178.601(g)(8), to ensure that minor variations in production processes do not result in different packagings. We are working with industry to define limits for fiberboard that may be considered identical to tested fiberboard. However, we have not received adequate industry input to establish specifics with regard to fiberboard boxes.

18) § 178.601: Section 178.601(f) states: "The manufacturer shall conduct the design qualification and periodic tests prescribed in this subpart using random samples of packagings, in the number specified in the appropriate test section." Section 178.601(k) states: "Provided the validity of the test results is not affected and with approval of the Associate Administrator for Hazardous Materials Safety, several tests may be performed on one sample." Is this indicating that a sample may only be used once? Or, for example could three drums used for the drop test also be used to conduct the hydrostatic pressure test?

The HMR do not prohibit the use of a single sample for more than one test, provided the correct number of samples is used for a particular test. In other words, samples which have been used for the stacking test or leakproofness test may be used to conduct the drop test or hydrostatic pressure test. The required number of samples must be maintained for each test; for example, six separate samples must be used for the drop test.

19) § 178.603: Would RSPA consider changing the pass criteria for the drop test to allow a momentary discharge of contents from inner packagings of combination packagings, as long as there is no continuous leakage, as is allowed for single packagings?

Under Docket HM-218 which was published in the Federal Register on August 18, 2000, [65 FR 50450] we revised § 178.603 to allow a slight discharge from a closure of a combination packaging if it ceases immediately after impact with no further leakage.

20) § 178.603: When conducting drop tests on drums and jerricans in accordance with § 178.603, does the closure need to be in the same position (example: 6 o'clock position) for each of the three top diagonal drop samples, or is the tester given latitude to rotate the closure during each of the three drops? And, again, for each of the three samples in the second orientation?

The HMR do not address the appropriate position of the closure of a drum regarding drop testing. Therefore, the tester may change the position of the closure for each of the three diagonal drops. When testing in the second orientation (the weakest part not tested by the first drop) the closure should be in the same position for each of the three drops.

21) § 178.603: Wouldn't being able to use less samples (using the same sample for multiple drops) be more severe than using a different sample for each drop? For example, a drum manufacturer manufactures a very low run, very expensive stainless steel drum. Why is it not more stringent for three drums to pass all six drops than using six drums? Why can this not be an acceptable alternative?

Although it may be a more stringent test to use one sample for more than one test, in developing the testing procedures we determined that a larger sample size provides a better assurance that all packagings of that design will be capable of passing the required test. In cases where the packagings are expensive or for small production runs, you may request an approval to use a reduced number of samples (see § 178.601(k)).

22) § 178.603: Do the packagings in § 178.522 (composite packagings with inner plastic receptacles) need to be conditioned at 0 degrees for 24 hours prior to the 178.603(e) drop test?

Yes. As provided by § 178.603(c), non-bulk single plastic packagings and plastic inner receptacles in composite and combination packagings must be subjected to the drop test at a temperature of –18°C (0°F) or lower. However, plastic bags intended to contain solids or articles need not be subjected to the temperature requirement.

23) § 178.606: Should the stack test for a UN1H2 plastic drum, used as a single packaging for solids or as an outer packaging for a combination packaging, be conducted for 24 hours at ambient conditions?

Yes. Drums intended for solid hazardous materials or inner packagings are required to be stacked for 24 hours. Plastic drums, jerricans and composite packagings intended to contain liquids must be stacked for 28 days (see § 178.606(c)(1)).

24) § 178.606(c): When performing the stack test on odd-shaped single units, is it permissible to place a single load spreader (e.g., a sheet of plywood) on top of all three units, with the total stack weight of on top of the spreader?

The acceptability of the test method indicated in the question would depend on the configuration of the packagings, including inner packagings of combination packagings which in many cases bear the force applied by the load. This method may not ensure that each packaging equally experiences the superimposed weight. However, if it can be shown that each packaging experiences equal loading, including inner packagings of combination packagings which are intended to bear any portion of the stacking load, it would be permissible to test in this configuration.

25) § 178.608: Is the vibration test specified in § 178.608 required? Must the packaging undergo a vibration test to be certified?

The vibration standard in § 178.608 is a capability standard. If you can determine through design evaluation, experience, or other means that the packaging is capable of passing the vibration standard you do not need to perform the test.

26) § 178.608: May a non-bulk packaging be tested with water only for the vibration test when certifying the packaging for transport of a hazardous material with a higher specific gravity?

As stated in the previous answer, the vibration standard in § 178.608 is a capability standard, not a test requirement. Water

may be used to perform testing to determine if a non-bulk packaging is capable of passing the vibration standard.

27) § 178.609(i): How often and what tests does an infectious substance packaging need to pass to be recertified? Is an infectious substance packaging subject to design type testing and periodic retest?

As provided by § 173.196(b) each packaging for an infectious substance must be capable of passing the tests specified in § 178.609. Currently there are no recertification requirements for these packagings in the HMR. However, under the ICAO Technical Instructions and the IMDG Code there are requirements for testing and marking of packagings used for infectious substances. Also, RSPA has proposed changes to the HMR which will require design type testing and periodic retesting when adopted in a final rule.

28) § 178.801: If a rigid intermediate bulk container has passed the vibration, top lift and/or bottom lift and stack tests but fails the leakproofness or hydrostatic pressure test, do the preceding tests need to be conducted again, even though they have no bearing on the IBC's leakproofness and internal pressure capabilities?

Yes, you must conduct the tests again because the HMR require that the tests be done sequentially (see § 178.803).

29) § 178.815: Should the stack test for a flexible intermediate bulk container be conducted for 24 hours?

No. Flexible IBCs must be subjected to a uniformly distributed superimposed test load for a period of at least five minutes (see § 178.815(c)).

30) § 178.819: Is filling an IBC with water only an acceptable practice for conducting the vibration test when certifying the IBC for transport of a hazardous material with a higher specific gravity?

We have determined that from a practicality and repeatability standpoint using water as the test medium is acceptable for IBC vibration testing even for materials with a high specific gravity. However, in actual practice a high specific gravity liquid may impart forces on the packaging that are not simulated by vibration testing with water.

31) § 178.819: If an IBC is going to be shipped on a flat bed trailer where chains and chain binders are used to secure the load, should the IBC be tested in the same configuration?
The attachment points of the chains may be the weakest link in this scenario and represent a more realistic test. Also, the IBC may vibrate to the point that it bounces off the platform.

When performing the vibration test on an IBC, § 178.819(b)(2) states the IBC must be constrained horizontally to prevent it from falling off the platform. It is not permissible to constrain an IBC in any other manner such as by chaining it to the vibration platform. You may however, use something on the ends of the table such as 2 X 4s to prevent the IBC from falling off the table. Federal Motor Carrier Safety requirements for securing loads to transport vehicles are set forth in 49 CFR 393.100 - 106.

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