

secondary container to consist of a 3 mil plastic bag with a reinforced fiberboard sleeve (open on the top and bottom) was sufficient. They also felt that requiring a reinforced bottom on the outer shipping container was unnecessary and would increase their production costs. The Postal Service feels these changes are necessary for safety reasons. At least two incidents have occurred in which the bottom of an auto-fold style outer shipping container gave way during postal handling causing the bagged primary receptacle to slide out of the reinforced sleeve and through the bottom of the outer shipping container. In this situation, the only level of protection from the primary container was the 3 mil plastic bag, which increased the safety risk to postal employees. For this reason, the Postal Service adopts the packaging change for regulated medical waste and sharps waste mailpieces that requires the secondary container be completely enclosed in a watertight container or containment system. The secondary container may consist of more than one component. If one of the components is a plastic bag, it must be at least 3 mil thick and be used in conjunction with a strong and securely sealed fiberboard box. A plastic bag by itself will not meet the requirement for a secondary container. The Postal Service also adopts the packaging change for regulated medical waste and sharps waste mailpieces to require that the bottom of the outer shipping container and all joints and flaps be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant.

One sharps mailer and the institute commented that the Postal Service proposed definition of "regulated medical waste" should also include sharps. Both felt that the Postal Service should not maintain a separate category for sharps waste since DOT had no such distinction. One commenter further stated that if sharps waste were included in the definition of regulated medical waste, then the Postal Service would only need one set of packaging requirements and mailers would not have to use different marking requirements for mailpieces containing regulated medical waste and sharps waste. The Postal Service does not agree with those arguments. Since the Postal Service began allowing medical waste in the mail more than ten years ago, there has been, and continues to be, a great deal of concern involving the potential dangers associated with sharps waste

should package failure occur during postal handling. The Postal Service has experienced a few instances in which a used syringe was found protruding from a sharps waste mailpiece that was not properly packaged prior to mailing. For this reason, the Postal Service will continue to maintain separate categories for sharps waste and other mailable types of regulated medical waste. This distinction will include separate requirements for the primary receptacles and different marking requirements for the outer shipping container. The Postal Service does not feel this will present a hardship on mailers since many already design and market their waste container systems for specific uses. It can also be noted that healthcare professionals generally do not mix sharps waste in the same containers used to collect other nonsharps medical waste.

Although not proposed by the Postal Service, one sharps waste mailer recommended the Postal Service require that sharps container systems be tested by "certified" labs, rather than by independent labs, as already permitted in DMM C023.8.7d. The Postal Service has not noted any significant problems with the use of independent labs, and therefore, sees no reason to adopt this recommendation. The problems associated with package failure of sharps waste container systems appear to be caused by container system design or the improper assembly of the container system by the end user prior to mailing.

The institute recommended that the Postal Service establish a "performance-based" standard for packaging rather than adopt new requirements for sealing the outer shipping container. The institute further suggested that the Postal Service allow a manufacturer or distributor to prove that their packaging material is safe when placed in the mail. We believe the commenter misinterpreted our intent and might not be aware of the preexisting requirements for package testing. The Postal Service has always required that packaging systems for sharps waste be tested by an independent testing facility using several of the tests detailed in 49 CFR part 178. Because the Postal Service has not experienced any significant problems with the test reports provided by the independent testing facilities, we do not feel there is a need to change the previously existing requirements for package testing. Additionally and as stated previously, the Postal Service will adopt new securing requirements for the outer shipping container to further reduce the potential for package failure during postal processing. The adoption of this requirement is directly

related to specific instances of package failure that have occurred during postal handling.

The institute also recommended that Postal Service require the assembly instruction sheet for each sharps container system also include a customer service telephone number for the end user to call if they need assistance or find a component part is missing. Although the Postal Service did not include this requirement in the proposed rule, it will adopt a variation of it in this final rule. The adopted text will require that each assembly sheet for a sharp waste or regulated medical waste container system list a customer service telephone number or provide specific information on where such a telephone number is located elsewhere on the container system. The Postal Service does not feel this will present a hardship for mailers, since many already display a customer service phone number on their assembly instruction sheets. The adoption of this requirement will help provide one more support level to the third-party end user who is being relied on to properly assemble the container system before depositing it into the mail. Proper assembly of a sharps container system prior to mailing is critical to ensuring it will be safely handled and transported without deterioration or package failure.

The institute further recommended that the Postal Service discontinue the use of the term "waste manifest" in the requirements that apply to the mailing of sharps waste and replace the term with "shipping paper." The Postal Service did not propose this change and feels it is unnecessary. The text in DMM C023.8.7c(3) states that the waste manifest serves as the shipping paper. In addition, such a change could pose a hardship for regulated medical waste and sharps waste mailers who presently identify this document as a waste manifest, by causing them to incur the cost for redesigning and replacing the documents.

#### *4. Comments Supporting the Proposed Changes*

Seven of the commenters, including three sharps mailers, two medical labs, the institute, and the law firm, submitted comments that supported some of the requirements in the Postal Service proposed rule. Those comments are summarized in this section.

Two of the sharps mailers stated that they did not oppose the Postal Service proposal to limit the maximum weight of a mailpiece containing regulated medical waste or sharps waste to 25 pounds. Another further stated that, in