

delayed effective date was needed to allow them and their clients a sufficient amount of time in which to use up preexisting packaging that is already in circulation. The Postal Service agrees that a phase-in period is needed and in this final rule has adopted an effective date of June 12, 2003, with a phase-in period through January 1, 2004. This phase-in period will allow for mailer implementation of the new packaging requirements for diagnostic (clinical) specimen mailpieces using a business reply mail format and regulated medical waste or sharps waste mailpieces using a merchandise return service format.

2. Comments Related to the Proposed Changes Affecting Diagnostic (Clinical) Specimens

Four commenters, including the three medical laboratories and the law firm, submitted comments related to the proposed requirements for clinical specimens.

Two of the medical labs and the law firm all maintained that the Postal Service proposal to require placement of the biohazard symbol on the primary container of a Risk Group 1, 2 or 3 diagnostic (clinical) specimen was impractical. They noted that mailers would incur added costs to place the symbol on the primary container. One commenter also noted that under the Federal requirements issued by the U.S. Department of Occupational Health and Safety Administration (OSHA), the biohazard symbol is required to appear on the secondary container. For these reasons, in this final rule the Postal Service has changed the placement requirement for the biohazard symbol on Risk Group 1, 2, and 3 specimens. For mailable types of Risk Group 1, 2, and 3 specimens, the biohazard symbol is required to appear on the secondary packaging, except in the instance where the secondary packaging also serves as the outer shipping container for a Risk Group 1 specimen. In that instance, then the biohazard symbol must appear on the inner packaging or on the primary container. The biohazard symbol must not appear on the outer shipping container of a mailable Risk Group 1, 2, or 3 specimen.

One of the medical labs opposed the Postal Service proposal to include diagnostic (clinical) specimens in the description of Division 6.2 materials in DMM C023.8.1 because they felt it could be confusing to most mailers. The text in DMM C023.8.1 is intended to generally identify the items that are described under the category of Division 6.2, some of which are regulated as infectious substances, and some of which are not. The definition of a

Division 6.2 material (infectious substance) is defined in DMM C023.8.2a, and that definition very closely mirrors the definition adopted by DOT in 49 CFR. The Postal Service does not feel that the general explanation in DMM C023.8.1 is confusing or misleading, but has made some minor changes to the text in the final rule for the purpose of clarity.

The same medical lab also asked whether it was the intent of the Postal Service to mirror the risk group classifications adopted by DOT. The answer is yes. The Postal Service believes this intent was clearly stated in the proposed rule, and it is also restated in Part C of this final rule. This commenter also asked whether the Postal Service classified all diagnostic (clinical) specimens collected for insurance purposes or through drug testing programs as Risk Group 1 materials. The Postal Service cannot make such a determination. In the proposed rule and in this final rule, the Postal Service has placed the responsibility for the proper determination of the Risk Group on the sender (*i.e.* generally the health care professional or individual who collects the specimen) as stated in DMM C023.8.2f. The Postal Service position on this point is in alignment with the stance DOT adopted in 49 CFR. The Postal Service suggests that packaging distributors include information to inform the collector of the specimen that the packaging may only be used to send Risk Group 1 specimens and that different packaging with stricter requirements must be used to send Risk Group 2, 3, or 4 specimens.

Another one of the medical labs that provided comments requested that the Postal Service clarify what materials are acceptable for a primary and secondary container holding a dry specimen. They also asked the Postal Service to clarify what would constitute a "securely sealed" primary receptacle in DMM C023.8.10b. Unlike the DOT regulations, the Postal Service proposed packaging requirements for dry clinical specimens since these types of specimens are routinely sent through the U.S. mail. Dry specimens often include materials such as saliva swabs, dried blood spots, and fecal smears. In the final rule, the Postal Service has made a few minor changes to the text for packaging a dry specimen in order to clarify the requirements. The Postal Service believes these changes are sufficient.

3. Comments Related to the Proposed Changes Affecting Regulated Medical Waste and Sharps Waste

Five parties, including the four sharps mailers and the institute, submitted comments related to the proposed changes affecting the mailing of regulated medical waste and sharps waste. For Postal Service purposes, regulated medical waste is defined in DMM C023.8.2e and sharps waste is defined in DMM C023.8.2g.

All four sharps mailers opposed the Postal Service proposal to limit the capacity of a sharps primary receptacle to a maximum of 3 gallons. Two commenters requested a limit of 5 gallons, one requested a limit of 11 gallons, and the other specified no maximum limit. Over the past few years, the Postal Service has experienced instances in which mailpieces containing sharps waste and having a 5-gallon primary receptacle have been found broken open in the mailstream. Although the number of incidents is small, the Postal Service believes that when properly designed and packaged prior to mailing, no approved sharps container should break open while in the mailstream. It was for this reason, and to ensure the safety of postal employees who handle these mailpieces, that the Postal Service proposed the new design requirement. The Postal Service does not agree with the commenters that a primary receptacle used to collect sharps (and designed for return via the U.S. mail) needs to be larger than 3 gallons in capacity. Most sharps container systems previously approved by the Postal Service have a primary receptacle with a capacity of less than 1 gallon. Primary receptacles having a capacity of 3 gallons or greater are not generally used to collect sharps waste for mail-back purposes, rather they are used to collect other types of nonsharps waste. Accordingly, the Postal Service will adopt a 3-gallon limit for a primary receptacle used to collect sharps waste as defined in DMM C023.8.2g and a 5-gallon limit for a primary receptacle used to collect regulated medical waste as defined in DMM C023.8.2e.

One sharps mailer opposed the Postal Service proposal to change the requirements for the secondary container for regulated medical waste and sharps waste packaging systems. The same sharps mailer also opposed the Postal Service proposal to prohibit easy-fold bottoms on outer shipping containers if they are not reinforced with a water-resistant tape. The commenter felt that the previous Postal Service requirement which allowed a