DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, 177, and 178

[Docket No. RSPA–98–3971 (HM–226)]

RIN 2137–AD13

Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-Organisms

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: RSPA is proposing to revise transportation requirements for infectious substances, including regulated medical waste, by adopting defining criteria and packaging requirements for infectious substances and genetically modified micro-organisms that are consistent with international standards; revising the current broad exceptions for diagnostic specimens and biological products; and authorizing bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions. These proposals are intended to assure an acceptable level of safety for the transportation of infectious substances and to facilitate domestic and international transportation.

DATES: *Comments.* Submit comments by April 23, 2001. To the extent possible, we will consider comments received after this date in making our decision on a final rule.

ADDRESSES: Submit comments to the Dockets Management System, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. Comments should identify Docket Number RSPA–98–3971 (HM–226) and be submitted in two copies. If you wish to receive confirmation of receipt of your written comments, include a self-addressed, stamped postcard. You may also submit comments by e-mail by accessing the Dockets Management System web site at ''http://dms.dot.gov/'' and following the instructions for submitting a document electronically.

The Dockets Management System is located on the Plaza level of the Nassif Building at the Department of Transportation at the above address. You can review public dockets there between the hours of 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. You can also review comments on-line at the DOT Dockets Management System web site at ''http://dms.dot.gov/.''

FOR FURTHER INFORMATION CONTACT: Eileen Edmonson or Susan Gorsky (202) 366–8553, Office of Hazardous Materials Standards, Research and Special Programs Administration.

SUPPLEMENTARY INFORMATION:

List of Topics

I. Background

On September 2, 1998, the Research and Special Programs Administration (RSPA, we) published an advance notice of proposed rulemaking (ANPRM) on revisions to the current requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) applicable to the transportation of infectious substances, Division 6.2, including regulated medical waste (63 FR 46844). We asked a variety of questions concerning classification criteria, hazard communication, and packaging requirements for infectious substances consistent with international standards; revisions to the current exceptions in the HMR for diagnostic specimens and biological products; and additional packaging requirements for regulated medical waste (RMW).

In addition, we conducted an electronic public meeting on the Internet from September 14–16, 1998, to facilitate public comment on the issues discussed in the ANPRM. For the Internet meeting, we posted the questions listed in the ANPRM and additional questions to encourage commenters to provide specific quantitative information relative to the transportation of infectious substances.

We received 89 comments in response to the ANPRM and the Internet meeting. Several commenters submitted more than one response. Most comments came from industry associations, colleges and universities, laboratories, and medical waste transporters. Comments were also submitted by state veterinary laboratories, state departments of agriculture, health insurance companies, a blood supplier, equipment suppliers, private citizens, a fire department, a union, and the U.S. Department of Agriculture.

II. Need for New Regulations

Many commenters question the need for increased regulation of infectious substances. They cite their experience with transporting these materials to support their view that there is little or no safety risk associated with such transportation and, thus, no justification for the changes proposed in the ANPRM. Commenters further assert that the proposed packaging and hazard communication requirements will impose significant transportation costs that are not justified by the safety risks involved with shipping infectious substances.

We do not agree that there is little risk associated with the transportation of infectious substances. RSPA's Hazardous Materials Information System (HMIS) includes reports of carriers discovering leaking, unlabeled packages containing blood and other potentially infectious material and of packages containing infectious materials being damaged in handling and releasing their contents. The Centers for Disease Control receives about 400 reports each year from carriers who detect leakage or other damage to packages of infectious substances. Releases of infectious substances in transportation present the possibility of exposure for transportation workers and the general public and can result in costly shipping delays and clean-up efforts.

Further, as a result of a provision in the accident reporting requirements in the HMR and the wording of the INFECTIOUS SUBSTANCE label, many releases of infectious substances are reported to CDC rather than to RSPA. Although the HMR require incident information reported to CDC also to be

reported to RSPA in a written incident report, carriers do not routinely do so. This has resulted in under-reporting of these incidents in RSPA's HMIS data base.

Over the last several years, individuals and companies commenting on infectious substances rulemakings or on their own initiative have reported information concerning infectious substance releases. These reports include blood pouring from roll-offs and freight containers transporting regulated medical waste (RMW), the disposal of HIV-contaminated blood in municipal waste cans, overturned vehicles that have released diagnostic specimens on highways, ruptured packages containing diagnostic specimens being transported by aircraft, releases of treatment-resistant diseases from inadequate packaging, and used sharps that puncture inner packagings.

Because of these reports and our own findings, we believe that the current regulatory requirements applicable to transportation of Division 6.2 materials should be strengthened. Accordingly, in this NPRM, we are proposing the following changes to the HMR:

- Adoption of new classification criteria for infectious substances based on defining criteria developed by the World Health Organization and consistent with standards contained in the United Nations Recommendations on the Transport of Dangerous Goods and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- Revision of current packaging requirements for Division 6.2 materials for consistency with international performance standards.
- Elimination of the current exception from requirements in the HMR for diagnostic specimens to impose certain packaging and hazard communication requirements. Diagnostic specimens transported in dedicated motor vehicles by private or contract carriers would continue to be excepted from most requirements in the HMR.
- Modification of the current exception from requirements in the HMR for biological products, limiting the exception to biological products licensed for use under current regulations of the Food and Drug Administration or U.S. Department of Agriculture.
- New transportation requirements for the transportation of genetically modified micro-organisms consistent with international requirements.
- New bulk packaging options for the transportation of RMW, based on current exemption provisions.
- New hazard communication requirements for shipments of Division 6.2 materials.

III. Summary of Proposals in NPRM

A. Classification Criteria for Infectious Substances

In the ANPRM, we indicated that we are considering revising the classification criteria for infectious substances consistent with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). In particular, we said we are considering adopting the risk groups and defining criteria developed by the World Health Organization (WHO) for Division 6.2 materials.

Commenters who support international harmonization of the classification criteria for infectious substances note that the proposal in the ANPRM would facilitate shipment of infectious substances in international commerce and by aircraft. Commenters opposed to the proposal are concerned about the possible misinterpretation and misapplication of the WHO risk group criteria. These commenters believe that the WHO risk group definitions are poorly worded and subject to broad interpretation and, as a result, assigning materials to risk group categories may be difficult or impossible.

As we stated in the ANPRM, the hazards posed by Division 6.2 materials vary greatly depending on the pathogenicity of the organism, the mode and relative ease of transmission, and other factors (63 FR 46845). It should be noted that determining if a material is infectious has always included subjective analysis in the absence of actual testing. Classifying these materials based on the level of risk and applying transportation requirements commensurate with that risk should ensure an adequate level of safety without imposing an undue burden on the regulated community. International harmonization of transportation standards also facilitates foreign trade and helps U.S. companies compete in the global economy. Most passenger and cargo air carriers currently require shipments of Division 6.2 materials to conform to the international standards.

Thus, in this NPRM, we are proposing to define Division 6.2 materials using the WHO risk group criteria. The proposal would require Division 6.2 materials to be assigned to risk groups based on the degree to which they cause injury through disease, with Risk Group 1 presenting the lowest risk and Risk Group 4 presenting the highest risk. Assignment to a risk group would be based on the known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning the individual circumstances of the patient or animal. Division 6.2 materials assigned to Risk Group 1 would be excepted from requirements in the HMR.

Commenters to the ANPRM are concerned that updated lists indicating risk group assignments for specific pathogens are difficult to obtain. We are aware of several organizations that maintain such lists. The American Biological Safety Association (ABSA) lists bacteria, fungi, viruses, and parasites according to their assigned risk groups. These lists can be found on-line at the ABSA web site (*http://www.absa.org/*). In addition, the ABSA web site includes links to risk group listings from Canada (in Health Canada's Laboratory Biosafety Guidelines at *http://www.hc-sc.gc.ca/hpb/lcdc/biosafty/docs/index.html)* and to Belguim's Biosafety Server (*http://biosafety.ihe.be/)*, which includes information on European regulation of infectious substances. The ABSA web site also includes information on the regulation of infectious substances in Australia, Brazil, Japan, and New Zealand at *http://biosafety.ihe.be/Menu/BiosWorld.html*. We plan to work with WHO and CDC to assure that updated guidance for determining the risk groups for specific materials is easily available.

B. Packaging Requirements for Infectious Substances

The HMR currently require an infectious substance to be packaged in a triple packaging that includes a water-tight primary receptacle, a water-tight secondary packaging, and an outer packaging. The primary receptacle or secondary packaging must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 95kPa (0.95 bar, 14 psi) and temperatures in the range of −40 °C to +55 °C (−40 °F to +131 °F). The triple packaging must be capable of passing the performance tests specified in § 178.609.

In this NPRM, we propose to incorporate several changes to the packaging requirements and performance tests to make them

consistent with the UN Recommendations and ICAO Technical Instructions. For example, we propose to require manufacturers to mark packagings represented as conforming to the specifications for infectious substances packagings in the HMR consistent with UN marking requirements. In addition, we propose to require manufacturers to retain packaging design qualification records and to retest packagings every 24 months. Further, we propose to replace the current requirement for a water immersion test with a water-spray test that simulates exposure to rainfall, as required by the ICAO Technical Instructions. Similarly, we propose to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions to allow variations in the primary receptacles within the secondary packaging without further testing of the completed package if an equivalent level of performance is maintained.

C. Exceptions for Domestic Shipments of Infectious Substances

In the September 1998 ANPRM, we noted that we are considering several exceptions from HMR requirements for domestic shipments of infectious substances by motor carrier. For example, the HMR include exceptions from most requirements of the HMR for hazardous materials transported as materials of trade. Materials of trade include hazardous materials carried by private motor carriers engaged in a principal business other than transportation, such as lawn care, plumbing, welding, and door-to-door sale of consumer goods. The materials of trade exception limits the maximum gross weight of materials of trade that may be carried on a motor vehicle and includes minimum packaging and hazard communication requirements.

In the ANPRM, we invited comments on expanding the materials of trade exception to permit certain biological products, diagnostic specimens, and RMW to be transported by private carriage as materials of trade. Commenters opposed to a materials of trade exception for infectious substances assert that such an exception would not provide an adequate level of safety for transporting infectious materials. Commenters who support a materials of trade exception note that it would reduce potential transportation costs, particularly if we remove the current exceptions in the HMR for diagnostic specimens and biological products.

In this NPRM, we are proposing to expand the materials of trade exceptions currently permitted under § 173.6 of the HMR to include certain biological products, diagnostic specimens, and RMW, including cultures and stocks. As proposed, this exception does not apply to materials known to contain or suspected of containing infectious substances in Risk Group 4.

The proposed exception specifies that the material must be contained in combination packagings consisting of one or more inner packagings inside an outer packaging. The capacity of each inner packaging may not exceed 0.5 kg (1.1 pound) or 0.5 L (17 ounces), and the capacity of the outer packaging may not exceed 4 kg (8.8 pounds) or 4 L (1 gallon). The proposed exception also permits combination packagings consisting of a single inner packaging with a capacity that does not exceed 16 kg (35.2 pounds) or 16 L (4.2 gallons) contained inside a single outer packaging. For RMW in combination packagings, each inner packaging may not exceed 4 kg (8.8 pounds) or 4 L (1 gallon) and the outer packaging may not exceed 16 kg (35.2 pounds) or 16 L (4.2 gallons). Under this proposal, infectious substances transported as materials of trade are subject to the general packaging, hazard communication, and motor vehicle operator notification requirements currently specified in § 173.6. The proposed materials of trade exception would apply to entities such as home health care providers and diagnostic laboratories that transport smaller amounts of infectious substances. We believe that the increased knowledge of the personnel handling these materials, most of whom are trained in the requirements of the Occupational Safety and Health Administration's (OSHA) Universal Precaution regulations for handling potentially contaminated material, will substantially reduce the risks associated with their transportation. In addition, the exception imposes minimum packaging requirements, at minimal cost, for materials currently excepted from the HMR.

D. Diagnostic Specimens

In the ANPRM, we proposed removing the existing broad exception from the HMR for diagnostic specimens and creating a regulatory system based on the WHO risk group definitions that requires diagnostic specimens to be packaged, described, and transported in a manner consistent with their level of risk. We proposed retaining the broad exception from the HMR for diagnostic specimens assigned to Risk Group 1 only. Further, we proposed exceptions to distinguish between a diagnostic specimen known or suspected to contain an infectious substance and one sent for routine testing.

The majority of comments we received in response to the ANPRM address the proposed regulations for diagnostic specimens. Most commenters oppose increased regulation for diagnostic specimens, suggesting that the proposed regulations are not justified by the safety record and will be difficult and costly to implement. Commenters further state that the proposed regulations could result in shipment delays, making early detection and treatment of disease difficult. Commenters note that shippers of diagnostic specimens may have little or no knowledge of what pathogens a given specimen may contain, making application of the WHO risk groups to such materials difficult, at best. Finally, commenters state that the proposed regulations could significantly increase health care costs.

Commenters who support regulation of diagnostic specimens note that releases of these materials do occur in transportation. These commenters generally support removal of the current exception from the HMR for diagnostic specimens to ensure packaging quality and to protect transportation workers and the general public from the risk of exposure to potentially infectious materials.

We agree with commenters that diagnostic specimens should be subject to regulation under the HMR. Our HMIS data base includes reports of packages containing these materials that were damaged in transportation, resulting in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. However, we also agree with commenters that the regulatory requirements proposed in the ANRPM could increase transportation costs for shipment of these materials.

Accordingly, in this NPRM, we are proposing regulations applicable to the transportation of diagnostic specimens that are consistent with proposed amendments to the UN Recommendations. We propose a new entry in the Hazardous Materials Table—''Diagnostic Specimen.'' There is no UN number, hazard warning label, or packing group assignment.

Under this proposal, diagnostic specimens meeting the definition of a Risk Group 4 material are classed and transported as Division 6.2 materials, UN 2814 or UN 2900. All other diagnostic specimens must be packaged in primary receptacles packed inside secondary packaging to preclude breakage, punctures, or leakage, and, for liquids, with sufficient absorbent

material to absorb the entire contents of the primary receptacle. The secondary packaging must be secured in outer packagings with suitable cushioning material. For liquids transported by aircraft, either the primary receptacle or the secondary packaging must be capable of withstanding an internal pressure producing a pressure differential of at least 95kPa (0.95 bar, 14 psi). The completed package must be capable of passing a drop test from a height of at least 1.2 meters (3.9 feet). The package must be marked with the words ''Diagnostic Specimens.'' Diagnostic specimens shipped in conformance with these proposed provisions are excepted from other requirements in the HMR, except that diagnostic specimens transported on board aircraft are subject to the incident reporting requirements in §§ 171.15 and 171.16. Under this proposal, offerors and transporters of diagnostic specimens must be informed of the diagnostic specimen packaging requirements.

In addition to the materials of trade exception discussed above, we are also proposing a complete exception from the HMR for diagnostic specimens transported by private or contract motor carriers. Based on comments received in response to the ANPRM, it is our understanding that most diagnostic specimens are shipped from collection sites (e.g., physicians' offices, nursing homes, clinics, etc.) to testing laboratories by private or contract couriers in dedicated vehicles. The couriers are familiar with the materials they transport and trained in the application of the OSHA Universal Precautions for handling materials that may contain infectious substances. Our proposal would require couriers to be informed about the materials they are transporting. This proposed exception will enable the transportation of diagnostic specimens quickly, efficiently, and safely to testing laboratories.

It should be noted that waste diagnostic specimens—that is, diagnostic specimens that meet the proposed definition for RMW in this NPRM—could not be transported under the exceptions proposed in this NPRM for the transportation of diagnostic specimens. Waste diagnostic specimens would lose their identity as diagnostic specimens for purposes of the HMR and would have to be transported in accordance with the HMR requirements applicable to RMW.

Taken together, we believe that these proposals for the transportation of diagnostic specimens are cost-effective, practical, and easy to understand and implement. Most important, these proposals will assure an adequate level of safety.

E. Biological Products

Commenters to the ANPRM generally support its proposals concerning transportation of biological products. Under current provisions, biological products are excepted from the HMR provided they meet Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA) regulations governing the transfer of biological products. In this NPRM, we propose to limit this exception to biological products that meet the definition of a Risk Group 1 material or are licensed for use under current FDA or USDA regulations. We propose to require unlicensed biological products meeting the definition of a Risk Group 2, 3, or 4 infectious substance to be classed as infectious substances, Division 6.2, and packaged in specification packagings authorized for the transportation of infectious substances.

In addition, we are proposing to add a special provision in § 172.102, consistent with ICAO Technical Instruction Special Provision A81, to except blood and blood products from current quantity limits for shipments by air when the materials are packaged in primary receptacles that do not exceed 500 ml (17 ounces) and contained in outer packagings not exceeding 4 L (1 gallon).

We also propose to except from all HMR requirements blood collected for blood transfusions, blood collected for the preparation of blood products, blood products intended for transplant, and tissues and organs intended for transplant.

It should be noted that waste biological products—that is, biological products that meet the proposed definition for RMW in this NPRM—may not be transported under the exceptions proposed in this NPRM for the transportation of biological products. Waste biological products lose their identity as biological products for purposes of the HMR and, if they contain infectious substances, must be transported in accordance with the HMR requirements applicable to RMW.

F. Genetically Modified Micro-Organisms

The UN Recommendations and the ICAO Technical Instructions treat any genetically modified micro-organism that meets the definition of a Division 6.2 material as an infectious substance. In addition, these international standards class a genetically modified micro-organism that does not meet the definition of a Division 6.2 material, but is capable of altering plants, animals, or microbiological substances in a way not normally the result of natural reproduction, as a Class 9 material. The UN Recommendations also contain a provision that excludes from regulation genetically modified micro-organisms that are authorized and licensed for use by the government of origin, transit, and destination.

In the ANPRM, we invited comment on whether the HMR should incorporate the international transportation standards for genetically modified micro-organisms. Commenters who addressed this issue are concerned that the proposed regulations could interfere with food and animal production. We appreciate their concerns, but we believe that the potential for environmental and property damage as a result of the release of genetically modified micro-organisms in transportation justifies their regulation as Class 9 materials.

Accordingly, in this NPRM, we propose to add ''Genetically modified micro-organism'' to the Hazardous Materials Table as a Class 9 material. Under this proposal, these materials must be packaged in conformance with the requirements for packaging infectious substances, except that the packagings need not be marked or tested in accordance with Part 178 requirements.

The NPRM proposes two exceptions applicable to the transportation of genetically modified micro-organisms. First, we propose to except genetically modified micro-organisms from all requirements in the HMR if a federal government agency authorizes their final distribution and use. Second, we propose to except genetically modified micro-organisms from HMR requirements when transported in a non-passenger-carrying transport vehicle operated by a private or contract motor carrier. The materials must be packaged to conform to the provisions described above, and the package must be marked with the proper shipping name ''Genetically modified micro-organism.'' Further, our proposal requires couriers to be informed about the materials they are transporting.

G. Regulated Medical Waste

Commenters generally support the proposals outlined in the ANPRM to permit transportation of RMW in non-specification bulk packagings. Currently, bulk packagings for the transportation of RMW are only authorized under the terms of 29 exemptions. For the most part, these

packagings have demonstrated that they provide an acceptable level of safety in transportation.

To ensure consistency with international regulations and to provide the broadest selection of authorized bulk packagings, we are also proposing to allow the use of ''Large Packagings,'' which are intermediate bulk packagings containing one or more inner packagings consistent with the requirements of the UN Recommendations. A definition for these packagings was proposed in an NPRM issued under Docket HM–215D, published October 23, 2000 (65 FR 63294) and in the International Maritime Dangerous Goods Code and ICAO's Technical Instructions. As proposed under HM–215D, a Large Packaging consists of an outer packaging containing articles or inner packagings and designed for mechanical handling. A Large Packaging has a capacity greater than 400 kg (882 lbs.) or 450 liters (119 gallons), but does not exceed 3 cubic meters in volume.

Accordingly, in this NPRM we propose to authorize Large Packagings and certain non-specification bulk containers for use as outer packagings for the transportation of RMW. Plastic film bags meeting performance and test requirements for impact and tear resistance are authorized as inner packagings for solid RMW. Inner packagings for liquid RMW must be rigid, leak resistant, puncture resistant, break resistant, impervious to moisture, and sealed to prevent leakage.

In addition to the above, we propose to revise the quantity limitations applicable to shipments of RMW on aircraft. Currently, such shipments are forbidden. We propose to revise the quantity limitations for non-bulk shipments of RMW on board aircraft to read ''No limit'' for consistency with the ICAO Technical Instructions applicable to quantity limitations for RMW on airplanes. We propose to continue to prohibit bulk shipments of RMW on board aircraft.

H. Used Health Care Products

One commenter suggests that the HMR include an exception for used health care products. The commenter states that used health care products potentially contaminated with infectious substances, such as wound care and sanitary products, surgical equipment, diagnostic and blood testing products, and contraceptives used by consumers, medical professionals, and pharmaceutical providers are routinely returned to manufacturers. Used health care products may be returned for assessment of clinical trials, new product development, customer complaints, product investigations for government compliance, service and repair, and competitor trade-ins.

The infectious status of many of these returned used health care products may not be known. An individual consumer may be unaware that he has an infectious disease or may be reluctant to reveal this information, or a patient may be infectious, but not symptomatic. In addition, patient confidentiality requirements prohibit health care providers from communicating a patient's infectious status to others.

Further, in the case of potentially contaminated used health care products, it is the inanimate product that is being shipped, not the infectious agent. While used health care products may be contaminated with human blood or other body fluids or tissues, these substances usually are dried on the health care product. Special conditions necessary to promote or sustain biological integrity are not available prior to or during shipment. If infectious agents are present on used health care products, they are, in the words of the commenter, ''unwanted hitchhikers'' and are subject to hostile conditions that may inactivate pathogens over time or, at least, do not support their amplification.

The commenter suggests that neither the HMR nor international standards clearly address the shipment of potentially contaminated used health care products. We agree. Thus, in this NPRM we are proposing to except used health care products being returned to the manufacturer from the requirements of the HMR provided the products are shipped in a triple packaging that conforms to certain manufacturing and marking requirements. Under this proposal, the primary and secondary containers must be marked with the OSHA BIOHAZARD symbol and must be constructed of metal or plastic in a manner that assures that they remain intact during transportation. Under this NPRM, offerors and transporters of used health care products potentially contaminated with an infectious substance must be informed about the used health care product packaging requirements.

I. Hazard Communication

In the ANPRM, we stated that we are considering several options with respect to the marking or placarding of bulk packagings and transport vehicles containing infectious substances, including RMW. Some commenters support a requirement for Division 6.2 placards on each vehicle or bulk packaging that contains any quantity of a Risk Group 4 infectious substance because of the extreme risks to emergency responders and the general public associated with the possible release of such material. These commenters also generally support a requirement for placards on all bulk shipments of infectious substances. Commenters who oppose placarding for shipments of infectious substances suggest that such a requirement is unnecessary, noting that there are significant differences in the potential harm that could result from a transportation incident involving infectious substances as compared to one involving flammable, toxic, or explosive materials.

We agree with commenters that communication of a Risk Group 4 hazard to transportation workers and emergency response personnel is important. However, we are concerned that placarding transport vehicles containing Risk Group 4 infectious substances could compromise the security of the shipments. Further, shipments of Risk Group 4 infectious substances are strictly controlled by CDC regulation. Thus, we are not proposing a placarding requirement in this NPRM.

However, we believe bulk packagings and transport vehicles containing RMW should be marked to communicate to emergency response personnel the nature of the material being transported. We are aware that a number of states and local governments have promulgated marking regulations applicable to the transportation of RMW. Many of these state and local regulations include a requirement for vehicles containing shipments of RMW to be identified with a marking similar to the BIOHAZARD symbol prescribed by OSHA regulations for containers of potentially infectious material. State, local, and tribal governments should be aware that the preemption provisions of Federal hazardous materials transportation law (federal hazmat law; 49 U.S.C. 5101 *et seq.*) generally preclude non-federal governments from imposing requirements applicable to hazardous materials transportation if such requirements are not consistent with the HMR. 49 U.S.C. 5125. Thus, in the absence of a waiver of preemption by the Secretary, where state or local requirements conflict with or are inconsistent with the HMR requirements, the HMR control.

Federal hazmat law codifies the ''dual compliance'' and ''obstacle'' criteria for preemption of non-federal regulations. As set forth in 49 U.S.C. 5125(a), these criteria provide that, in the absence of a waiver of preemption by the Secretary

under 49 U.S.C. 5125(e) or unless it is authorized by another federal law, a requirement of a state, political subdivision of a state, or Indian tribe is explicitly preempted if:

(1) complying with a requirement of the state, political subdivision or Indian tribe and a requirement of Federal hazardous materials transportation law or a regulation issued under the law is not possible; or

(2) the requirement of the state, political subdivision, or Indian tribe, as applied or enforced, is an obstacle to accomplishing and carrying out Federal hazardous materials transportation law or a regulation prescribed under the law.

Federal hazmat law also includes additional preemption provisions on certain ''covered subject'' areas. The covered subject areas are:

(a) The designation, description, and classification of hazardous material.

(b) The packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(c) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(d) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(e) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container represented, marked, certified, or sold as qualified for use in transporting hazardous material. 49 U.S.C. 5125(b).

Marking is a covered subject for purposes of preemption. Thus, unless authorized by another federal law or a waiver of preemption from the Secretary of Transportation, a non-federal marking requirement is preempted when it is not ''substantively the same'' as federal hazmat law or a regulation issued under it. 49 U.S.C. 5125(b)(1).

In the interest of uniformity, we believe it is essential that state, local, and tribal marking requirements be consistent from jurisdiction to jurisdiction. Thus, in this NPRM, we propose to require bulk packagings containing RMW to be marked with the appropriate UN identification number. We are also proposing to require bulk packagings of RMW to be identified with a BIOHAZARD marking that conforms to OSHA specifications for the BIOHAZARD marking in 29 CFR 1910.1030(g)(1)(i).

In this NPRM, we are also proposing to revise the INFECTIOUS SUBSTANCE label to reflect the new toll-free number to report infectious substances incidents to the CDC. That toll-free number is 1–800–232–0124.

J. Petitions for Rulemaking

The ANPRM requested comments on a petition for rulemaking (P–1350) submitted by the Medical Waste Institute (MWI) requesting relief for transportation of waste cultures and stocks that meet the definition for Division 6.2 materials. Specifically, MWI requests that we revise the HMR to allow contract and private motor carriers to transport discarded cultures and stocks of infectious substances in non-specification packagings if the carriers use dedicated vehicles. Currently, under § 173.134(b)(3), the HMR allow this type of transportation for RMW that does not contain a culture or stock of an infectious substance.

In support of its petition, MWI states that the current packagings required in the HMR for discarded cultures and stocks are not justified because they are expensive and lack a safety record that proves their actual public health and safety benefits. With its petition, MWI includes HMIS and state incident data on infectious substances for the period 1989 through March 1997.

Experience under exemption DOT–E 11588 has demonstrated that Packing Group II packagings transported by a private or contract carrier in dedicated vehicles provide an acceptable level of protection for waste cultures and stocks of infectious substances. Private and contract carriers that transport these materials have an increased level of knowledge about these materials. Moreover, the use of dedicated vehicles limits public exposure and assures that packages are handled by experienced personnel. We also have found that the general packaging requirements in §§ 173.24 and 173.24a, coupled with OSHA's packaging requirements in 29 CFR 1910.1030 for bloodborne pathogens, are adequate for less virulent types of infectious substances. Therefore, in this NPRM, we are proposing to revise § 173.134(b) to permit transportation of waste cultures and stocks of Risk Group 2 or 3 infectious substances in non-specification packagings when transported by private or contract carriers in dedicated vehicles.

IV. Section-by-Section Review

Part 171

Section 171.7

We propose to revise the table of material incorporated by reference to add two new references to test methods developed by the American Society for Testing and Materials. These tests would be required for plastic inner packagings used to transport RMW inside Large Packagings and non-specification bulk packagings.

Section 171.8

We propose to add definitions for ''biological product,'' ''cultures and stocks,'' ''diagnostic specimen,'' ''genetically modified micro-organism,'' ''risk group,'' ''sharps,'' and ''toxin.'' These definitions would refer readers to the definitions in Part 173 of the HMR.

Section 171.14

We propose to allow a two-year transition period for Division 6.2 labels revised as proposed in this NPRM.

Section 171.15

We propose to remove the term ''etiologic agents'' from paragraphs (a)(3) and (b) and replace it with ''infectious substances.'' In addition, in paragraph (b) we propose to add wording to emphasize that a written report of an incident involving infectious substances must be submitted to RSPA.

Part 172

Section 172.101

For the entry ''Regulated medical waste,'' we propose to remove the letter ''D'' in column (1). In column (7), we propose to remove the reference to Special Provision A14 and to revise columns (9A) and (9B) to replace ''Forbidden'' with ''No Limit'' for quantity limitations on board aircraft. These proposed changes harmonize requirements in the HMR with those in the ICAO Technical Instructions and facilitate the transportation of RMW in non-bulk packagings by aircraft. In addition, column 8C is revised to replace ''none'' with 197, to indicate that bulk packagings authorized for the transportation of RMW can be found in § 173.197 of the HMR. Finally, we propose to revise Special Provision A13 to prohibit the transportation of bulk packagings of RMW by aircraft.

For the entries ''Infectious substances, affecting animals only'' and ''Infectious substances, affecting humans,'' we propose to add new special provisions in column (7). Special Provision A81 provides relief from quantity limits for the transport of blood or blood products that contain infectious substances when in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4L (1 gallon) and packaged in accordance with § 173.196. Special Provision A82 provides relief from UN standard packaging for transporting body parts, whole organs, and whole bodies.

We propose to add a new entry, ''Genetically modified micro-organism,'' to the Table as a Class 9 material consistent with entries in the UN Recommendations, ICAO Technical Instructions, and International Maritime Dangerous Goods Code.

In addition, we propose to add a new entry, ''Diagnostic specimen'', to the Table as a Division 6.2 material. There is no UN number, hazard warning label, or packing group assignment.

We also propose to add two new entries for ''Toxins, liquid, extracted from living sources, n.o.s., UN 3172'' and ''Toxins, solid, extracted from living sources, n.o.s., UN 3172.'' For both entries, a ''G'' in column (1) indicates that the shipping description on shipping papers must include the technical names for the materials. Both entries indicate that the materials are Division 6.1 materials, UN 3172, PG I, II, or III. We propose to add Special Provision 141 to state that toxins that contain infectious substances or are contained in infectious substances must be classed as Division 6.2 materials and assigned to UN 2814 or UN 2900, as appropriate.

Section 172.102

We propose to revise this section by removing Special Provision A14, revising Special Provision A13, and adding Special Provisions 141, A81, and A82, as detailed above.

Section 172.323

We propose to add this section to require bulk packagings containing RMW to be marked with a BIOHAZARD marking conforming to OSHA regulations at 29 CFR 1910.1030.

Section 172.432

We propose to revise the INFECTIOUS SUBSTANCE label to incorporate the new toll-free telephone number (1–800–232–0124) for reporting incidents to the CDC.

Part 173

Section 173.6

We propose to add a materials of trade exception for diagnostic specimens, biological products, and RMW, other than Risk Group 4 materials. The proposed exception includes packaging requirements and quantity limitations.

Section 173.28

We propose to require Division 6.2 packagings to be decontaminated prior to reuse.

Section 173.134

In paragraph (a), we propose to revise the definitions and classification criteria for ''infectious substance,'' ''biological product,'' ''diagnostic specimen,'' and ''regulated medical waste'' and to add definitions for ''cultures and stocks,'' ''risk group,'' ''sharps,'' and ''toxin.''

We propose to revise the definition of ''infectious substance'' for consistency with international standards and to require materials meeting the definition of an infectious substance to be assigned to risk groups based on the degree to which they cause injury through disease. Infectious substances assigned to Risk Group 1 are not subject to regulation under the HMR.

We propose to revise the definition of ''biological product'' to require biological products known to contain or suspected to contain a pathogen in Risk Groups 2, 3, or 4 to be classed as Division 6.2 materials, unless otherwise excepted.

We propose to define ''cultures and stocks'' to mean a material that is prepared and maintained for growth and storage and that contains a Risk Group 2, 3, or 4 infectious substance.

We propose to revise the definition of ''diagnostic specimen'' to require a diagnostic specimen known to contain or suspected to contain a Risk Group 4 pathogen to be classed as a Division 6.2 material. This determination is based on the known medical history and condition of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning the individual circumstances of the patient or animal.

We propose to revise the definition for ''regulated medical waste'' to indicate that regulated medical waste is a waste or reusable material that contains or is suspected to contain a Risk Group 2 or 3 infectious substance. As proposed in this NPRM, regulated medical waste containing a Risk Group 4 infectious substance must be classed and transported as a Division 6.2 material, UN 2900 or UN 2814.

We propose to define ''risk group'' to mean a ranking of a micro-organism's ability to cause injury through disease. Risk group assignment criteria include the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of effective preventive agents and treatments.

We propose to define ''sharps'' to mean any object that may be contaminated with an infectious substance that is also able to cut or penetrate the skin or packaging material. The term includes needles, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

We propose to define ''toxin'' to mean a Division 6.1 material secreted from a plant, animal, or bacterial source. The proposed definition notes that toxins that contain an infectious substance or are contained in an infectious substance must be classed as Division 6.2 materials.

In paragraph (b), we propose to list exceptions from the HMR requirements applicable to Division 6.2 materials. Proposed exceptions include:

1. Biological products licensed/approved for public dissemination by FDA or USDA;
2. Blood collected for transfusions or the preparation of blood products, and blood products, tissues, and organs intended for transplant;
3. Diagnostic specimens or biological products transported by private or contract motor carriers in dedicated motor vehicles;
4. Material treated so that it no longer contains an infectious substance;
5. Sanitary waste and sewage;
6. Sewage sludge and compost;
7. Animal waste generated in animal husbandry or food production;
8. Corpses and anatomical parts intended for interment, cremation, or research; and
9. Forensic material transported on behalf of the federal government or a state, local government, or tribal government agency.

We also propose to modify the exception for medical waste generated from households to indicate that such medical waste must be transported in accordance with applicable state, local, or tribal government requirements.

In addition, we propose to revise the exception for laundry or medical equipment conforming to OSHA regulations in 29 CFR 1910.1030 to clarify that this exception applies to medical equipment intended for reuse and equipment used for testing. The revised definition further clarifies that the exception does not apply to medical equipment transported for disposal.

In paragraph (c), we propose to modify the exception for RMW transported by contract or private carriers to include waste cultures and stocks that contain Risk Group 2 or 3 infectious substances.

Finally, we propose to add paragraph (d) to clarify that if an item listed in paragraphs (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and

transported in accordance with applicable requirements of the HMR.

Section 173.140

We propose to add new paragraphs (c) and (d) to provide defining criteria and exceptions for genetically modified micro-organisms that do not meet the definition of a Division 6.2 material, but that have the potential to alter animals, plants, or the environment. These materials are assigned to the Class 9 hazard class. Genetically modified micro-organisms that meet the criteria for a Division 6.2 material must be classed as infectious substances. We propose to except genetically modified micro-organisms from HMR requirements if a federal government agency authorizes their final distribution and use. We also propose to except genetically modified micro-organisms from HMR requirements when transported in a non-passenger-carrying transport vehicle operated by a private or contract motor carrier.

Section 173.196

We propose to revise this section for clarity and consistency with the UN Recommendations and ICAO Technical Instructions. These revisions include packaging and overpack marking requirements to ensure the integrity of the packagings during air transport, including circumstances where the refrigerant is dissipated or lost. A new paragraph (d) is added to prescribe non-specification packaging provisions for body parts.

Section 173.197

We propose to revise this section to authorize certain bulk packagings for the transportation of RMW. Paragraph (a) proposes general requirements for both non-bulk and bulk packagings. Proposed paragraph (b) requires non-bulk packagings to conform to the requirements of part 178 at the Packing Group II performance level. Proposed paragraphs (c) and (d) authorize Large Packagings and non-specification bulk containers for the transportation of RMW. These proposed packaging provisions are based on the terms of 29 current exemptions and our own initiative. Proposed paragraph (c) sets forth conditions governing the use of Large Packagings. Proposed paragraph (d) sets forth the conditions governing the use of non-specification wheeled carts and bulk outer packagings. Proposed paragraph (e) specifies the inner packagings authorized for use with bulk outer packagings.

Section 173.199

We propose to add a new § 173.199 to address packaging requirements for diagnostic specimens and used health care products. Diagnostic specimens meeting the definition of a Risk Group 4 material must be classed and transported as infectious substances, UN 2814 or UN 2900. Generally, we propose to permit all other diagnostic specimens to be shipped in triple packagings that are capable of passing a 1.2 meter (3.9 feet) drop test.

We propose to require liquid diagnostic specimens to be packaged in leakproof primary receptacles with a volumetric capacity of not more than 500 ml (17 ounces). For shipments by aircraft, the primary receptacle or secondary packaging must be able to withstand without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The secondary packaging must be leakproof and impervious to moisture. The volumetric capacity of the outer packaging may not exceed 4 L (1 gallon).

We propose to require solid diagnostic specimens to be packaged in a siftproof primary receptacle with a capacity of not more than 500 g (1.1 pounds). The secondary packaging must be leakproof. The capacity of the outer packaging may not exceed 4 kg (8.8 pounds).

We propose to permit shipment of used health care products being returned to the manufacturer in triple packagings, in which the primary and secondary containers must be constructed of plastic or metal and must be marked with the OSHA BIOHAZARD symbol. A used health care product that can cut or penetrate skin or packaging material must be transported in a puncture-resistant primary container.

Under this proposal, diagnostic specimens and used health care products shipped in accordance with these provisions are not subject to any other requirements in the HMR, except for minimal training requirements and, for diagnostic specimens, incident reporting for shipments offered for transportation or transported by aircraft.

Section 173.200

We propose to add a new § 173.200 to address packaging requirements for genetically modified micro-organisms. We propose to require genetically modified micro-organisms to be packaged in conformance with § 173.196, except that the packagings need not be marked in accordance with § 178.503 nor tested in accordance with § 178.609. Alternatively, we propose to permit genetically modified micro-organisms to be transported in packagings that meet the specifications in §§ 173.203 or 173.213 at the Packing Group III performance level.

Part 177

Section 177.834

We propose to revise paragraphs (a) and (g) to indicate that packages containing Division 6.2 materials must be properly secured in a transport vehicle.

Section 177.843

We propose to add a new paragraph (d) to require a transport vehicle to be decontaminated prior to reuse if a Division 6.2 material is released from its packaging inside the vehicle.

Part 178

Section 178.503

We propose to add a new paragraph (f) to incorporate package markings for infectious substances packagings consistent with those in the ICAO Technical Instructions and the UN Recommendations.

Section 178.601

We propose to add a sentence to paragraph (c)(1) of this section to include the tests for infectious substance packaging in the definition of design qualification testing. As a result of this proposed change, manufacturers of infectious substances packagings are required to retain design qualification records in accordance with § 178.601(c)(l). In addition, we propose to add a sentence to paragraph (c)(2) to indicate that, for infectious substances packagings, periodic retesting is the performance of tests specified in § 178.609 at the frequency specified in § 178.601(e). Finally, we propose to add a sentence to paragraph (e) to require packagings used to transport infectious substances to pass periodic retests.

Section 178.609

We propose to revise the section heading to remove the wording ''(etiologic agents).'' We propose to revise paragraph (c) to permit the use of expanded plastics for inner packagings and require the packaging tests to be determined by the most fragile inner packaging. Paragraphs (d)(1)(i), (d)(1)(iii), and (d)(1)(iv) are revised for clarity. We propose to revise paragraph (e) to replace the current water immersion test with a water spray test that simulates exposure to rainfall consistent with the ICAO Technical Instructions. Paragraphs (h)(1) and (h)(2) are revised to clearly indicate that,

during the penetration test, penetration of the primary receptacle is not acceptable. Current paragraph (i) is deleted. We propose to add new paragraph (i) to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions. These provisions allow variations in the primary receptacles within the secondary packaging without further testing of the completed packaging if an equivalent level of performance is maintained.

V. Regulations of Other Agencies

In addition to RSPA, several federal agencies have responsibility for regulating infectious substances and genetically modified micro-organisms.

A. Centers for Disease Control and Prevention

The Department of Health and Human Services is authorized to promulgate regulations to prevent the introduction, transmission, and spread of communicable diseases in the United States. CDC has been delegated authority to regulate the interstate shipment of infectious substances. The current CDC regulations are codified at 42 CFR Part 72. The regulations provide requirements for minimum packaging and labeling for diagnostic specimens and biological products, and include a list of select agents for which special labeling and tracking is required.

On October 28, 1999, CDC published an NPRM, proposing to clarify and expand existing requirements for proper packaging and handling of infectious substances (64 FR 58022). The NPRM includes proposals to ensure that all biological materials known or suspected to contain an infectious substance are packaged to minimize the potential for leakage during transit. The proposed regulations are intended to harmonize CDC regulations with those of other federal agencies and with international standards.

B. Occupational Safety and Health Administration

The Department of Labor's Occupational Safety and Health Administration (OSHA) is authorized to assure safe and healthy workplaces by the Occupational Safety and Health Act of 1970 (OSH Act). OSHA regulations governing occupational exposure to bloodborne pathogens in human blood and body fluids, unfixed tissues, organs, cell cultures, and other fluids from humans or animals are codified at 29 CFR Part 1910.1030. The regulations require persons who handle bloodborne pathogens to utilize Universal Precautions as a means of infection control. The Universal Precautions require human blood and body fluids to be treated as if known to be infectious. Among other requirements, the regulations require specimens of blood or other potentially infectious materials to be placed in containers that prevent leakage during collection, handling, processing, storage, or transport. The regulations also require containers of potentially infectious material to be labeled with a BIOHAZARD label.

C. Food and Drug Administration

The Food and Drug Administration (FDA) regulates, licenses, and approves biological and related products to ensure their purity, potency, safety, and efficacy. FDA regulates vaccines, blood derivatives, allergenic extracts, blood components, whole blood, tissues, monoclonal antibodies, biotech derived products, somatic cell and gene therapies, in vitro diagnostics, and medical devices. FDA's regulations are codified at 21 CFR Parts 1–1299.

D. U.S. Department of Agriculture

The U.S. Department of Agriculture's (USDA) Center for Veterinary Biologics assures that pure, safe, potent, and effective veterinary biological products are available for the diagnosis, prevention, and treatment of animal diseases. The program assures that biological products are free of disease-producing agents, develops appropriate standards and procedures for product release, issues licenses and permits, monitors and inspects products and facilities, and controls field tests and the release of veterinary biological products. USDA regulations for veterinary biological products are codified at 9 CFR parts 101–124.

Several USDA agencies regulate and monitor the use of biotechnology for agriculture. The Animal and Plant Health Inspection Service regulates the movement, importation, and field testing of Genetically Engineered Organisms (GEOs) through permitting and notification procedures. The Food Safety Inspection Service has responsibility for the safe use of engineered domestic livestock, poultry, and products derived from them. The Agricultural Research Service conducts in-house research on GEOs. The Cooperative State Research, Education, and Extension Service administers the biotechnology risk assessment program as well as research programs in gene mapping, sequencing and biotechnology applications. USDA regulations applicable to GEOs are at 7 CFR part 340.

E. Actions to Assure Regulatory Consistency

A number of commenters to the ANPRM urged us to work with other federal agencies to assure that regulations applicable to the transportation of infectious substances are compatible. We agree that persons who offer for transportation or transport infectious substances or genetically modified micro-organisms should not be forced to comply with several sets of inconsistent or conflicting regulations imposed by different federal regulatory agencies. We met with CDC to discuss its 1999 NPRM and potential areas of conflict with the HMR and international standards. In addition, we provided CDC, USDA, FDA, and OSHA with copies of our NPRM in advance of publication in the **Federal Register** for their information and comment, and asked specifically for potential areas of conflict between their regulations and the proposals in this NPRM. None of these agencies identified any potentially conflicting regulatory requirements in their informal responses to our request. We encourage commenters to address this issue as well.

VI. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is not a significant regulatory action under Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. This proposed rule is not a significant regulatory action under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). A preliminary regulatory evaluation that considers various regulatory alternatives is available for review in the public docket.

The costs of these proposed regulations identified in the regulatory evaluation are attributed to the regulation of shipments of diagnostic specimens that include a Risk Group 2, 3 or 4 pathogen. Our tentative estimate of costs is slightly more than $2 million per year.

Because of a lack of reliable information concerning deaths, injuries, property damage, and other costs attributable to incidents involving the release of an infectious substance, we are unable to quantify potential savings that may result from these proposed rules, if adopted as final. Affected parties and other concerned persons are requested to provide comments on costs and/or potential benefits.

Benefits resulting from implementation of the NPRM proposals include the following:

1. *International harmonization:* Harmonization of requirements in the HMR with standards specified in the UN Recommendations, ICAO Technical Instructions, IMDG Code, and TDG will remove current inconsistencies among the regulations, thereby facilitating efficient transportation of infectious substances across national borders. More importantly, harmonized regulations reduce the potential for misunderstanding and confusion and, thus, enhance safety.

2. *Conversion of exemptions to regulations of general applicability:* Conversion of 29 exemptions applicable to the bulk transportation of RMW to regulations of general applicability will result in a slight cost savings to the 29 exemptions holders and 65 parties-to-the-exemption holders. In addition, the industry will be able to take advantage of the added flexibility provided by the increased number of packaging options for transporting RMW.

3. *Modification of current exceptions for diagnostic specimens and biological products:* We believe that potentially infectious diagnostic specimens and biological products should not be transported without regard to packaging and with no communication of hazard to those who may come into contact with them. The HMIS data base and anecdotal information indicate that packages of these currently excepted materials are sometimes damaged during transportation, resulting in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. The proposed requirements in the NPRM for more stringent packaging for these materials combined with the proposed exceptions for transportation of these materials as materials of trade or by private or contract carriers in dedicated vehicles will assure swift and efficient transportation while reducing the risks to transportation workers and the general public. Enhancements to packaging would also reduce the risk of exposure for laboratory workers opening and handling packages at the point of receipt. The minimal level of regulation proposed for these materials would enhance overall safety while imposing insignificant costs on the regulated industry.

4. *New requirements for genetically modified micro-organisms:* We believe that genetically modified micro-organisms that have not been approved for distribution should not be transported without regard to packaging and communication of hazard. Thus, we are proposing new packaging and hazard communication requirements for these currently unregulated materials. The proposal to incorporate into the HMR international standards applicable to genetically modified micro-organisms will enhance transportation safety and reduce potential adverse environmental impacts while imposing minimal requirements on the regulated industry.

Although we cannot assign definitive dollar amounts to these potential benefits, we believe that, taken together, the proposals are the least costly alternatives available for ensuring an acceptable level of transportation safety and that the potential benefits to society more than offset the potential costs associated with this proposed rule.

B. Executive Order 13132

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This proposed rule would preempt state, local, and Indian tribe requirements but does not propose any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazardous materials transportation law, 49 U.S.C. 5101–5127, contains an express preemption provision (49 U.S.C. 5125(b)) that preempts state, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This proposed rule addresses covered subject items 1–5 above and would preempt state, local, and Indian tribe requirements not meeting the ''substantively the same'' standard. This proposed rule is necessary to assure an acceptable level of safety for the transportation of infectious substances and facilitate international transportation of these materials.

Federal hazardous materials transportation law provides at section 5125(b)(2) that, if DOT issues a regulation concerning any of the covered subjects, DOT must determine and publish in the **Federal Register** the effective date of federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. We propose that the effective date of federal preemption be one year from publication of a final rule in the **Federal Register**.

C. Executive Order 13084

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because this proposed rule does not significantly or uniquely affect the communities of the Indian tribal governments and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13084 do not apply.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. Based on the assessment in the preliminary regulatory evaluation, I hereby certify that while the proposed rule would apply to a substantial number of small entities, there would not be a significant economic impact on those small businesses. This certification is based upon a consideration that the identified costs are randomly distributed to the more than 441,000 establishments (offices and clinics of doctors of medicine, dentists, doctors of osteopathy, chiropractors, optometrists, podiatrists, and health practitioners; nursing and personal care facilities; hospitals; and medical and dental laboratories) that comprise Standard Industrial Classification (SIC) Major Group 80 (Health Services). The slightly more than $2 million in annual costs attributed to this proposed rule is a mere fraction of the $300 billion in receipts reported by the health services industry. We believe none of those costs will be disproportionately borne by any of the identified groups of small businesses. If your business or organization is a small entity and if adoption of some or all of the proposed

provisions could have a significant economic impact on your operations, please submit a comment to explain how and to what extent your business or organization could be affected.

E. Paperwork Reduction Act

RSPA has current information collection approvals under OMB No. 2137–0039, Hazardous Materials Incident Reports, which expires March 31, 2002, with 33,811 burden hours and $811,221.66 annual costs; and OMB No. 2137–0557, Approvals for Hazardous Materials, which expires August 31, 2003, with 180,302 burden hours and $413,737.40 annual costs. We believe that this proposed rule may result in an increase in annual burden hours and costs. If these proposals are finalized, the current approvals would be required to be revised and resubmitted to OMB for extension and re-approval.

Section 1320.8(d), Title 5, Code of Federal Regulations requires RSPA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collections that we may submit to OMB for extension and re-approval based on the requirements in this proposed rule. We have revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in this proposed rule since the information collection was last approved. We estimate that the total information collection and recordkeeping burden as proposed in this rule would be revised as follows:

OMB No.: 2137–0039.
Total Annual Responses: 22,900.
Total Annual Burden Hours: 34,441.
Total Annual Burden Cost: $825,621.66.

OMB No.: 2137–0557.
Number of Respondents: 3,523.
Total Annual Responses: 3,875.
Total Annual Burden Hours: 18,405.
Total Annual Burden Cost: $415,237.40.

We specifically request comments on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these requirements for approval under this proposed rule.

Requests for a copy of the information collection should be directed to Deborah Boothe, Office of Hazardous Materials Standards (DHM–10), Research and Special Programs Administration, Room 8102, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone (202) 366–8553.

Written comments should be addressed to the Dockets Unit as identified in the **ADDRESSES** section of this rulemaking. Comments should be received prior to the close of the comment period identified in the **DATES** section of this rulemaking. Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it displays a valid OMB control number. If these proposed requirements are adopted in a final rule, RSPA will submit the revised information collection and recordkeeping requirements to the Office of Management and Budget for approval.

F. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

G. Unfunded Mandates Reform Act

This NPRM imposes no mandates and thus does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995.

H. Environmental Assessment

We find that there are no significant environmental impacts associated with this proposed rule. An environmental assessment has been placed in the public docket for this rulemaking.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 177

Hazardous materials transportation, Motor carriers, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, we propose to amend 49 CFR parts 171, 172, 173, 177, and 178 as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR part 1.

2. In § 171.7, in the table in paragraph (a)(3), two new entries would be added in alphanumeric sequence under the American Society for Testing and Materials, to read as follows:

§ 171.7 Reference material.

(a) * * *

(3) *Table of material incorporated by reference.* * * *

Source and name of material	49 CFR reference
* * * * * * *	
American Society for Testing and Materials	
* * * * * * *	
ASTM D 1709–97 Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method, 1997 Edition	173.197
* * * * * * *	
ASTM D 1922–94A Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method, 1994 edition	173.197
* * * * * * *	

* * * * *

3. Section 171.8 would be amended by adding the following definitions in alphabetical order to read as follows:

§ 171.8 Definition and abbreviations.

* * * * *

Biological product. See § 173.134 of this subchapter.

* * * * *

Cultures and stocks. See § 173.134 of this subchapter.

* * * * *

Diagnostic specimen. See § 173.134 of this subchapter.

* * * * *

Genetically modified micro-organism. See § 173.140 of this subchapter.

* * * * *

Risk group. See § 173.134 of this subchapter.

* * * * *

Sharps. See § 173.134 of this subchapter.

* * * * *

Toxin. See § 173.134 of this subchapter.

* * * * *

4. Section 171.14 would be amended by adding paragraph (f) to read as follows:

§ 171.14 Transitional provisions for implementing certain requirements.

* * * * *

(f) Division 6.2 labels that conform to specifications in § 172.432 of this subchapter in effect on October 1, 2000, may be used until [two years from the effective date of final rule].

§ 171.15 [Amended]

5. In § 171.15, the following changes would be made:

a. Paragraph (a)(3) would be amended by removing the term ''(etiologic agents)''.

b. Paragraph (b) introductory text would be amended by removing the term ''etiologic agents'' and in its place adding the term ''infectious substances''.

c. Paragraph (b) introductory text would be amended by adding the wording ''; however, a written report is still required as stated in paragraph (c) of this section'' immediately after the number ''202–267–2675''.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

6. The authority citation for part 172 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

7. In § 172.101, the following proper shipping names would be added, in alphabetical order, or revised in the Hazardous Materials Table to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

§ 172.101.—HAZARDOUS MATERIALS TABLE

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification Numbers	PG	Label codes	Special provisions	(8) Packaging (§ 173.* * *)			(9) Quantity limitations		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/ rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[ADD]												
	Diagnostic specimen.	6.2				A82	134	199	None	4L or 4kg	4L or 4kg	A	40
	* *			*		*		*		*		*	
	Genetically modified micro-organisms.	9	UN3245		9		140	200	None	No Limit	No Limit	A	40
	* *			*		*		*		*		*	
G	Toxins, liquid, extracted from living sources n.o.s.	6.1	UN3172	I	6.1	141		201	243	1 L	30 L	B	40
				II				202	243	5 L	60 L	B	40
				III			153	203	241	60 L	220 L	A	40
G	Toxins, solid, extracted from living sources n.o.s.	6.1	UN3172	I	6.1	141		211	243	5 kg	50 kg	B	
				II				212	243	25 kg	100kg	B	
				III			153	213	241	100 kg	200kg	A	
	* *			*		*		*		*		*	
	[REVISE]												
G	Infectious substances, affecting animals *only*.	6.2	UN2900		6.2	A81, A82	134	196	None	50 ml or 50 g	4L or 4kg	B	40
G	Infectious substances, affecting humans.	6.2	UN2814		6.2	A81, A82	134	196	None	50 ml or 50 g	4L or 4kg	B	40
	* *			*		*		*		*		*	
	Regulated medical waste.	6.2	UN3291	II	6.2	A13	134, 197	197	197	No Limit	No Limit	A	40
	* *			*		*		*		*		*	

* * * * *

8. In § 172.102, in paragraph (c)(1), Special provision 141 would be added, and in paragraph (c)(2), Special Provision A13 would be revised, Special provision A14 would be removed, and Special Provisions A81 and A82 would be added in alphanumeric order to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

Code/Special Provisions

* * * * *

141 A toxin from a plant, animal or bacterial source that contains an infectious substance, or a toxin that is contained in an infectious substance, must be classed as Division 6.2 and assigned to UN 2814 or UN 2900, as appropriate.

(2) * * *

Code/Special Provisions

* * * * *

A13 Bulk packagings are not authorized for transportation by aircraft.

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A81 The quantity limits in columns (9A) and (9B) do not apply to blood or blood products known to contain or suspected of containing an infectious substance when transported in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4 L (1 gallon) and packaged in accordance with § 173.196 of this subchapter. A82 The quantity limits in columns (9A) and (9B) do not apply to human or animal body parts, whole organs or whole bodies known to contain or suspected of containing an infectious substance.

* * * * *

9. A new § 172.323 would be added to read as follows:

§ 172.323 Infectious substances.

(a) In addition to any identification number required by this subpart, a bulk packaging containing a regulated medical waste, as defined in § 173.134(a)(5) of this subchapter, must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i)—

(1) On two opposing sides or two ends other than the bottom if the packaging has a capacity of less than 3,785 L (1,000 gallons). The BIOHAZARD marking must measure at least 273 mm (10.8 inches) on each side and must be visible from the direction it faces.

(2) On each end and each side if the packaging has a capacity of 3,785 L (1,000 gallons) or more. The BIOHAZARD marking must measure at least 273 mm (10.8 inches) on each side and must be visible from the direction it faces.

(b) For a bulk packaging contained in or on a transport vehicle or freight container, if the BIOHAZARD marking on the bulk packaging is not visible, the transport vehicle or freight container must be marked as required by paragraph (a) of this section on each side and each end.

10. In § 172.432, the illustration in paragraph (a) would be revised to read as follows:

§ 172.432 INFECTIOUS SUBSTANCE label.

(a) * * *

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PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

11. The authority citation for part 173 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127, 44701; 49 CFR 1.45, 1.53.

12. In § 173.6, paragraph (a)(1) introductory text would be revised, paragraph (a)(4) would be redesignated as paragraph (a)(5), and a new paragraph (a)(4) would be added to read as follows:

§ 173.6 Materials of trade exceptions.

* * * * *

(a) * * *

(1) A Class 3, 8, 9, Division 4.1, 5.1, 5.2, 6.1, 6.2, or ORM–D material contained in a packaging having a gross mass or capacity not over—

* * * * *

(4)(i) A Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product or regulated medical waste. The material must be contained in a combination packaging consisting of—

(A) One or more inner packagings where the gross mass or capacity of each inner packaging does not exceed 0.5 kg (1.1 pound), or 0.5 L (17 ounces), and an outer packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon); or

(B) A single inner packaging with a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons) in a single outer packaging.

(ii) Regulated medical waste may be packaged in a combination packaging consisting of inner packagings having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon), and an outer packaging having a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons). Packagings intended to contain sharps must be resistant to puncture and leak resistant.

* * * * *

13. Section 173.28 would be amended by adding paragraph (f) to read as follows:

§ 173.28 Reuse, reconditioning and remanufacture of packagings.

* * * * *

(f) A Division 6.2 packaging that is to be reused must be decontaminated prior to reuse by any means that is effective for neutralizing the infectious substance the packaging previously contained. A secondary packaging or outer packaging that conforms to the requirements of § 173.196 or § 173.199 need not be decontaminated prior to reuse if no leakage from the primary receptacle has occurred.

14. Section 173.134 would be revised to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions and exceptions.

(a) *Definitions and classification criteria.* For the purpose of this subchapter, the following definitions and classification criteria apply:

(1) *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen that has the potential to cause disease when exposure to it occurs. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro-organisms (hybrid or mutant) that cause infectious disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph (a). Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(2) *Biological product* means:

(i) A Division 6.2 material that is derived from a living organism that includes, but is not limited to, materials manufactured and distributed in accordance with one of the following provisions:

(A) 9 CFR part 102 (Licenses for Biological Products);

(B) 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing);

(C) 9 CFR part 104 (Permits for Biological Products);

(D) 21 CFR part 312 (Investigational New Drug Application); or

(E) 21 CFR parts 600 to 680 (Biologics).

(ii) A *biological product* is used for prevention, treatment, or diagnosis of disease in humans or animals, or for developmental, experimental, or investigational purposes related to these uses. This term includes a finished product such as a vaccine or an unfinished product intended for further processing into a finished product; however, it does not include a diagnostic specimen. Biological products known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material that is prepared and maintained for growth and storage and that contains a Risk Group 2, 3 or 4 infectious substance.

(4) *Diagnostic specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A *diagnostic specimen* is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 micro-organism, in which case it must be assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(5) *Regulated medical waste* means a waste or reusable material that contains or is suspected of containing an infectious substance in Risk Group 2 or 3 and is generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment or immunization of human beings or animals; or the production or testing of biological products. *Regulated medical waste* containing an infectious substance in Risk Group 4 must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate.

(6) *Risk group* means a ranking of a micro-organism's ability to cause injury through disease. A *risk group* is defined by criteria developed by the World Health Organization (WHO) based on the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a *risk group* and a packing group. The criteria for each *risk group* according to the level of risk are as follows:

RISK GROUP TABLE

Risk group	Pathogen	Risk to individuals	Risk to the community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	HIGH	HIGH
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	HIGH	LOW
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	MODERATE	LOW
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	NONE OR VERY LOW	NONE OR VERY LOW

(7) *Sharps* means any object that may be contaminated with a pathogen that is also capable of cutting or penetrating skin or a packaging material. The term includes needles, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

(8) *Toxin* means a Division 6.1 material secreted from a plant, animal, or bacterial source. A *toxin* that contains an infectious substance or a *toxin* that is contained in an infectious substance must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate.

(b) *Exceptions.* The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(1) Biological products that are known to contain or suspected of containing a pathogen in Risk Group 1, or that do not contain a pathogen.

(2) Biological products that have successfully completed all applicable

federal approval or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.

(3) Blood that has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products, tissues, or organs intended for use in transplant operations.

(4) A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure/contamination to the diagnostic specimen. If a diagnostic specimen or biological product meets the definition of regulated medical waste in paragraph (a)(5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(5) Laundry or medical equipment that conforms to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment that is intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment that is being transported for disposal.

(6) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer meets the definition of an infectious substance.

(7) A living person.

(8) Any waste or recyclable material, other than regulated medical waste, including—

(i) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(ii) Sanitary waste or sewage;

(iii) Sewage sludge or compost;

(iv) Animal waste generated in animal husbandry or food production; or

(v) Medical waste generated from households and transported in accordance with applicable state, local, or tribal requirements.

(9) Corpses, remains, and anatomical parts that are intended for interment, cremation, or medical research at a college, hospital, or laboratory.

(10) Forensic material that is transported on behalf of a U.S. Government, state, local or Indian tribal government agency. The material must be shipped in a packaging conforming to the provisions of § 173.24.

(c) *Exceptions for regulated medical waste.* The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste that is transported by a private or contract carrier is excepted from—

(i) The requirement for an ''INFECTIOUS SUBSTANCE'' label if the outer packaging is marked with a ''BIOHAZARD'' marking in accordance with 29 CFR 1910.1030; and

(ii) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of this section if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030.

(2) A waste culture or stock of a Risk Group 2 or 3 infectious substance may be offered for transportation and transported as a regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier using a vehicle dedicated to the transportation of regulated medical waste.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.

15. Section 173.140 would be amended by removing ''; or'' at the end of paragraph (a) and adding a period in its place and by adding paragraphs (c) and (d) to read as follows:

§ 173.140 Class 9-Definitions.

* * * * *

(c) *Genetically modified micro-organism.* A genetically modified micro-organism is a micro-organism that has been purposely altered through genetic engineering in a way that does not occur naturally.

(1) A Class 9 genetically modified micro-organism does not meet the definition of a Division 6.2 material, but has the potential to alter animals, plants or microbiological substances in a way not normally the result of natural reproduction.

(2) A genetically modified micro-organism that also meets the definition for a Division 6.2 material must be classed as a Division 6.2 material.

(3) A live animal that contains, or is contaminated with, a genetically modified micro-organism, including a genetically modified micro-organism that also meets the definition of a Division 6.2 material, must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(4) A genetically modified micro-organism known or suspected to be dangerous to the environment may not be transported by air unless approved by the Associate Administrator for Hazardous Materials Safety.

(d) *Exceptions for genetically modified micro-organisms.* (1) A genetically modified micro-organism that is authorized by a U.S. Government agency for final distribution and use is not subject to requirements of this subchapter.

(2) A genetically modified micro-organism is excepted from all other requirements of this subchapter when transported in a non-passenger carrying transport vehicle operated by a private or contract motor carrier. The material must be packaged in accordance with the provisions in § 173.203 or § 173.213 at the Packing Group III performance level, and marked with the proper shipping name ''Genetically modified micro-organism''. Each person who offers or transports a genetically modified micro-organism under the provisions of this paragraph (d) must be informed of the requirements of this paragraph (d).

16. Section 173.196 would be revised to read as follows:

§ 173.196 Infectious substances.

(a) *Division 6.2 packaging.* A Division 6.2 packaging must meet the test standards of § 178.609 of this subchapter and must be marked in conformance with § 178.503(f) of this subchapter. Division 6.2 packaging is a triple packaging that consists of the following components:

(1) A watertight primary receptacle.

(2) A watertight secondary packaging. If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually to prevent contact between them.

(3) An outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must

measure at least 100 mm (3.9 inches) at its smallest overall external dimension.

(4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.

(5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.

(6) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) and temperatures in the range of −40 °C to +55 °C (−40 °F to +131 °F).

(b) *Additional requirements for packaging infectious substances.* Infectious substances must be packaged according to the following requirements depending on the physical state and other characteristics of the material:

(1) *Infectious lyophilized substances.* Primary receptacles must be flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.

(2) *Liquid or solid infectious substances*—(i) *Infectious substances shipped at ambient temperatures or higher.* Authorized primary receptacles are those of glass, metal, or plastic. Positive means of ensuring a leakproof seal, such as heat seal, skirted stopper, or metal crimp seal, must be provided. If screw caps are used, they must be secured by positive means, such as with adhesive tape.

(ii) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside the secondary packagings or in an overpack with one or more complete packages marked in accordance with § 178.503 of this subchapter. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were lost.

(iii) *Infectious substances shipped in liquid nitrogen.* Primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were to be lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks (also called ''dry shippers'') vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in § 172.312(b) of this subchapter must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal that contains or is contaminated with an infectious substance must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging that meets the requirements of § 173.197(a).

17. Section 173.197 would be revised to read as follows:

§ 173.197 Regulated medical waste.

(a) *General provisions.* Non-bulk and bulk packagings used for the transportation of regulated medical waste must be rigid containers that meet the provisions of subpart B of this part. The packaging must be puncture-resistant for sharps and sharps with residual fluid as demonstrated by conducting the performance tests in part 178, subpart M, of this subchapter on packagings containing materials representative of the sharps and fluids (such as sterile sharps) that are intended to be transported in the packagings.

(b) *Non-bulk packagings.* Except as otherwise provided in this subchapter, non-bulk packagings for regulated medical waste must conform to the requirements of part 178 of this subchapter at the Packing Group II performance level.

(c) *Large packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements of the UN Recommendations and conforming to other requirements of this paragraph (c) may be used for the transportation of regulated medical waste, provided that the inner packagings conform to the requirements of paragraph (e) of this section. Each Large Packaging must be capable of meeting the vibration test specified in § 178.819 of this subchapter. Each Large Packaging is subject to the periodic design requalification requirements for intermediate bulk containers in § 178.801(e) of this subchapter and to the proof of compliance requirements of § 178.801(j) and record retention requirements of § 178.801(l) of this subchapter. Inner packagings used for liquids must be rigid.

(1) *Authorized packagings.* The following Large Packagings are authorized for the transportation of liquid or solid regulated medical waste:

(i) Metal: 50A, 50B, or 50N.

(ii) Rigid plastic: 50H.

(2) *Additional requirements.* Each Large Packaging used to transport liquid regulated medical waste must contain absorbent material in sufficient quantity and appropriate location to absorb the entire amount of liquid present in the event of an unintentional release of contents. Each Large Packaging intended for the transportation of sharps containers must be puncture resistant and capable of retaining liquids and must meet the performance tests specified for intermediate bulk containers intended for the transportation of liquids in subpart O of part 178 of this subchapter.

(d) *Non-specification bulk packaging.* A wheeled cart (CART) or bulk outer packaging (BOP) is authorized as an outer packaging for the transportation of regulated medical waste in accordance with the provisions of this paragraph (d).

(1) *General requirements.* The following requirements apply to the transportation of regulated medical waste in CARTs or BOPs:

(i) Each CART or BOP must have non-bulk inner packagings that conform to paragraph (e) of this section.

(ii) Each CART or BOP must have interior surfaces that are smooth, non-porous, and free of cracks, crevices, and other defects that could damage inner packagings or impede decontamination operations.

(iii) Except as otherwise provided in this paragraph (d), each CART or BOP

must be used exclusively for the transportation of regulated medical waste. Prior to reuse, each CART or BOP must be decontaminated by any means that is effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated cultures and stocks of infectious substances that contain Risk Group 4 materials may not be transported in a CART or BOP.

(v) Division 6.1 toxic waste or Class 7 radioactive waste, with the exception of materials that are chemotherapeutic waste, may not be transported in a CART or BOP.

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated stocks and cultures of infectious substances that contain Risk Group 2 or 3 pathogenic organisms; unabsorbed liquids; and sharps containers may be transported in a CART or BOP only if packaged in rigid non-bulk packagings that conform to paragraph (a) of this section.

(2) *Wheeled cart (CART).* A CART is authorized as an outer packaging for the transportation of regulated medical waste if it conforms to the following requirements:

(i) Each CART must consist of a solid, one-piece body, mounted on a minimum of four (4) fixed wheels, with a nominal volume that does not exceed 1,655 liters (437 gallons).

(ii) Each CART must be constructed of metal, rigid plastic, or fiberglass with a hinged and gasketed lid that, when closed, prevents leakage during transport.

(iii) Each CART must be capable of meeting the requirements of § 178.603 (drop test), as specified for solids at the Packing Group II performance level.

(iv) Inner packagings must be placed into a CART and restrained in such a manner as to minimize the risk of breakage.

(3) *Bulk outer packaging (BOP).* A BOP is authorized as an outer packaging for regulated medical waste if it conforms to the following requirements:

(i) Each BOP must be constructed of metal or fiberglass and have a capacity of at least 3.5 cubic meters (123.6 cubic feet) and not more than 45 cubic meters (1,590 cubic feet).

(ii) Each BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top that prevents the intrusion of water (e.g., rain or snow).

(iii) Each opening in a BOP must be fitted with a closure that prevents the intrusion of water or the release of any liquid during all loading, unloading, and transportation operations.

(iv) In the upright position, each BOP must be leakproof and able to contain a liquid quantity of at least 300 liters (79.2 gallons) with closures open.

(v) Inner packagings must be placed in a BOP in such a manner as to minimize the risk of breakage. Rigid inner packagings may not be placed in the same BOP with plastic film bag inner packagings unless separated from each other by rigid barriers or dividers that prevent damage to the packagings caused by load shifting during normal conditions of transportation.

(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated cultures and stocks of infectious substances that contain Risk Group 2 or 3 pathogenic organisms, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as provided by paragraph (d)(3)(v) of this section.

(e) *Inner packagings authorized for Large Packagings, CARTs, and BOPs.* Inner packagings must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, CART, or BOP originates at a single location and is delivered to a single location.

(1) *Solids.* A plastic film bag is authorized as an inner packaging for solid regulated medical waste transported in a CART, Large Packaging, or BOP. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent material to absorb and retain all liquid during transportation.

(i) The film bag may not exceed a volume of 175 L (46 gallons). The film bag must be marked and certified by its manufacturer as having passed the tests prescribed for tear resistance in ASTM D 1709–97, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method,* 1997 Edition, and for impact resistance in ASTM D 1922–94A, *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method,* 1994 edition. The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.

(ii) The plastic film bag must be closed with a minimum of entrapped air to prevent leakage in transportation. The bag must be capable of being held in an inverted position with the closed end at the bottom for a period of 5 minutes without leakage.

(iii) When used as an inner packaging for CARTs or BOPs, a plastic film bag may not weigh more than 10 kg (22 lbs.) when filled.

(2) *Liquids.* Liquid regulated medical waste that is transported in a Large Packaging, CART, or BOP must be packaged in a rigid inner packaging that conforms to the requirements of paragraph (a) of this section. Liquid materials are not authorized for transportation in inner packagings larger than 19 L (5 gallons).

(3) *Sharps.* Sharps that are transported in a Large Packaging, CART, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each inner packaging may not exceed 38 L (10 gallons) in volume.

18. A new § 173.199 would be added to read as follows:

§ 173.199 Diagnostic specimens and used health care products.

(a) *Diagnostic specimens.* Diagnostic specimens are excepted from other requirements of this subchapter when offered for transportation or transported in accordance with this section. Diagnostic specimens offered for transportation or transported by aircraft under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter. A diagnostic specimen that meets the definition of a hazard class other than Division 6.2 must be offered for transportation or transported in accordance with applicable requirements of this subchapter.

(1) Diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, a secondary packaging, and an outer packaging.

(2) Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging.

(3) Secondary packagings must be secured in outer packagings with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

(4) The completed package must be capable of successfully passing the drop test in § 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Each package must be clearly and durably marked with the words ''Diagnostic Specimen.''

(b) *Liquid diagnostic specimens.* Liquid diagnostic specimens must be packaged in conformance with the following provisions:

(1) The primary receptacle must be leakproof with a volumetric capacity of not more than 500 ml (16.9 ounces).

(2) Absorbent material must be placed between the primary receptacle and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles.

(3) The secondary packaging must be leakproof.

(4) For shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(5) The outer packaging may not exceed 4 L (1 gallon) capacity.

(c) *Solid diagnostic specimens.* Solid diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, secondary packaging, and outer packaging, that conforms to the following provisions:

(1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds).

(2) If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them.

(3) The secondary packaging must be siftproof.

(4) The outer packaging may not exceed 4 kg (8.8 pounds) capacity.

(d) *Used health care products.* Used health care products are medical, diagnostic, or research devices and equipment, and personal care products used by consumers, medical professionals, or pharmaceutical providers that may be contaminated with an infectious substance but do not meet the definition of a diagnostic specimen, biological product, or regulated medical waste. Used health care products being returned to the manufacturer are excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this section. For purposes of this section, a health care product is used when it has been removed from its original inner packaging. Used health care products contaminated with or suspected of contamination with a Risk Group 4 infectious substance may not be transported under the provisions of this section.

(1) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight metal or plastic primary container. The primary container must be designed and constructed in such a manner as to assure that it remains intact under conditions normally incident to transportation. Each primary container used to transport a used health care product that is capable of cutting or penetrating skin or packaging material must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i).

(2) Each primary container must be placed inside a watertight metal or plastic secondary container. The secondary container must be designed and constructed in such a manner as to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i).

(3) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.

(e) *Training.* Each person who offers or transports a diagnostic specimen or used health care product under the provisions of this section must be informed of the requirements of this section.

19. A new § 173.200 would be added to read as follows:

§ 173.200 Genetically modified micro-organisms.

A genetically modified micro-organism must be packaged as follows:

(a) In accordance with the provisions in § 173.203 or § 173.213 for liquids or solids, respectively, at the Packing Group III performance level; or

(b) In accordance with the provisions of § 173.196(a), except that the completed package is not subject to the test requirements in § 178.609 of this subchapter.

PART 177—CARRIAGE BY PUBLIC HIGHWAY

20. The authority citation for part 177 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

21. In § 177.834, paragraphs (a) and (g) would be revised to read as follows:

§ 177.834 General requirements.

(a) *Packages secured in a vehicle.* Any tank, barrel, drum, cylinder, or other packaging not permanently attached to a motor vehicle that contains any Class 2 (gases), Class 3 (flammable liquid), Division 6.1 (poisonous), Division 6.2 (infectious substance), Class 7 (radioactive), or Class 8 (corrosive) material must be secured against movement within the vehicle on which it is being transported, under conditions normally incident to transportation.

* * * * *

(g) *Prevent relative motion between containers.* Containers of Class 1 (explosive), Class 2 (gases), Class 3 (flammable liquid), Class 4 (flammable solid), Class 5 (oxidizing), Division 6.1 (poisonous), Division 6.2 (infectious substance), or Class 8 (corrosive) materials must be so braced as to prevent motion thereof relative to the vehicle while in transit. Containers having valves or other fittings must be so loaded that there will be the minimum likelihood of damage thereto during transportation.

* * * * *

22. In § 177.843, new paragraph (d) would be added to read as follows:

§ 177.843 Contamination of vehicles.

* * * * *

(d) Each transport vehicle used to transport Division 6.2 materials must be decontaminated prior to reuse if a Division 6.2 material is released from its packaging during transportation. Decontamination may be by any means that is effective for neutralizing the material released.

PART 178—SPECIFICATIONS FOR PACKAGINGS

23. The authority citation for part 178 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

24. In § 178.503, paragraph (f) would be added to read as follows:

§ 178.503 Marking of packagings.

* * * * *

(f) A manufacturer must mark every UN specification package that is represented as manufactured to meet the requirements of § 178.609 for packaging of infectious substances with the marks specified in this section. The markings must be durable, legible, and must be readily visible, as specified in § 178.3(a). An infectious substance packaging that

successfully passes the tests conforming to the UN standard must be marked as follows:

(1) The United Nations symbol as illustrated in paragraph (e) of this section.

(2) The code designating the type of packaging and material of construction according to the identification codes for packagings specified in § 178.502.

(3) The text ''CLASS 6.2''.

(4) The last two digits of the year of manufacture of the packaging.

(5) The country authorizing the allocation of the mark. The letters ''USA'' indicate that the packaging is manufactured and marked in the United States in compliance with the provisions of this subchapter.

(6) The name and address or symbol of the manufacturer or the approval agency certifying compliance with subparts L and M of this part. Symbols, if used, must be registered with the Associate Administrator for Hazardous Materials Safety.

(7) For packagings meeting the requirements of § 178.609(i)(3), the letter ''U'' must be inserted immediately following the marking designating the type of packaging and material required in paragraph (f)(2) of this section.

25. In § 178.601, paragraphs (c)(1), (c)(2), and (e) would be revised to read as follows:

§ 178.601 General requirements.

* * * * *

(c) * * *

(1) *Design qualification testing* is the performance of the tests prescribed in § 178.603, § 178.604, § 178.605, § 178.606, § 178.607, § 178.608, or § 178.609, as applicable, for each new or different packaging, at the start of production of that packaging.

(2) *Periodic retesting* is the performance of the drop, leakproofness, hydrostatic pressure, and stacking tests, as applicable, as prescribed in § 178.603, § 178.604, § 178.605, or § 178.606, respectively, at the frequency specified in paragraph (e) of this section. For infectious substances packagings that are required to meet the requirements of § 178.609, periodic retesting is the performance of the tests specified in § 178.609 at the frequency specified in paragraph (e) of this section.

* * * * *

(e) *Periodic retesting.* The packaging manufacturer must achieve successful test results for the periodic retesting at intervals established by the manufacturer of sufficient frequency to ensure that each packaging produced by the manufacturer is capable of passing the design qualification tests. Changes in retest frequency are subject to the approval of the Associate Administrator for Hazardous Materials Safety. For single or composite packagings, the periodic retests must be conducted at least once every 12 months. For combination packagings, the periodic retests must be conducted at least once every 24 months. For infectious substances packagings, the periodic retests must be conducted at least once every 24 months.

* * * * *

26. In § 178.609, the section heading, paragraph (c) preceding the table, the introductory text of paragraph (d)(1), paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (e), (h)(1), (h)(2), and (i) would be revised to read as follows:

§ 178.609 Test requirements for packagings for infectious substances.

* * * * *

(c) Packagings prepared as for transport must be subjected to the tests in Table I of this paragraph (c), which, for test purposes, categorize packagings according to their material characteristics. For outer packagings, the headings in Table I relate to fiberboard or similar materials whose performance may be rapidly affected by moisture; plastics, which may embrittle at low temperature; and other materials, such as metal, for which performance is not significantly affected by moisture or temperature. Where a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of more than one material, the material most likely to be damaged determines the appropriate test.

* * * * *

(d) * * *

(1) Where the samples are in the shape of a box, five must be dropped in sequence:

(i) Flat on the base;

(ii) * * *

(iii) Flat on the longest side;

(iv) Flat on the shortest side; and * * * * *

(e) The samples must be subjected to a water spray that simulates exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

* * * * *

(h) * * *

(1) Samples must be placed on a level, hard surface. A cylindrical steel rod with a mass of at least 7 kg (15 pounds), a diameter not exceeding 38 mm (1.5 inches), and, at the impact end edges, a radius not exceeding 6 mm (0.2 inches), must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the impact end of the sample's impact surface. One sample must be placed on its base. A second sample must be placed in an orientation perpendicular to that used for the first. In each instance, the steel rod must be aimed to impact the primary receptacle(s). There must be no leakage from the primary receptacle(s) following each impact.

(2) Samples must be dropped onto the end of a cylindrical steel rod. The rod must be set vertically in a level, hard surface. It must have a diameter of 38 mm (1.5 inches) and a radius not exceeding 6 mm (0.2 inches) at the edges of the upper end. The rod must protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm (7.9 inches). One sample must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the top of the steel rod. A second sample must be dropped from the same height in an orientation perpendicular to that used for the first. In each instance, the packaging must be oriented so that the steel rod will impact the primary receptacle(s). There must be no leakage from the primary receptacle(s) following each impact.

(i) *Variations.* The following variations in the primary receptacles placed within the secondary packaging are allowed without additional testing of the completed package. An equivalent level of performance must be maintained.

(1) *Variation 1.* Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided they meet all of the following conditions:

(i) The primary receptacles are of similar design to the tested primary receptacle (*e.g.,* shape: round, rectangular, etc.).

(ii) The material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and a stacking force equal to or greater than that of the originally tested primary receptacle.

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (*e.g.,* screw cap, friction lid, etc.).

(iv) Sufficient additional cushioning material is used to fill void spaces and to prevent significant movement of the primary receptacles.

(v) Primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(2) *Variation 2*. A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in paragraph (i)(1) of this section, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

(3) *Variation 3*. Primary receptacles of any type may be placed within a secondary packaging and shipped without testing in the outer packaging provided all of the following conditions are met:

(i) The secondary and outer packaging combination must be successfully tested in accordance with paragraphs (a) through (h) of this section with fragile (*e.g.,* glass) inner receptacles.

(ii) The total combined gross weight of inner receptacles may not exceed one-half the gross weight of inner receptacles used for the drop test in paragraph (d) of this section.

(iii) The thickness of cushioning material between inner receptacles and between inner receptacles and the outside of the secondary packaging may not be reduced below the corresponding thicknesses in the originally tested packaging. If a single inner receptacle was used in the original test, the thickness of cushioning between the inner receptacles must be no less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material must be used to fill the void.

(iv) The outer packaging must pass the stacking test in § 178.606 while empty. The total weight of identical packages must be based on the combined mass of inner receptacles used in the drop test in paragraph (d) of this section.

(v) For inner receptacles containing liquids, an adequate quantity of absorbent material must be present to absorb the entire liquid contents of the inner receptacles.

(vi) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not sift proof, a means of containing any liquid or solid contents in the event of leakage must be provided. This can be a leakproof liner, plastic bag, or other equally effective means of containment.

(vii) In addition, the marking required in § 178.503(f) of this subchapter must be followed by the letter ''U''.

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Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration.

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