

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

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

ACTION: Final rule.

SUMMARY: RSPA is revising transportation requirements for infectious substances, including regulated medical waste, to: adopt defining criteria and packaging requirements consistent with international standards; revise the current broad exceptions for diagnostic specimens and biological products; and authorize bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions. These revisions will assure an acceptable level of safety for the transportation of infectious substances, and facilitate domestic and international transportation.

DATES: *Effective Date:* This final rule is effective October 1, 2002.

Voluntary Compliance Date: Voluntary compliance is authorized 30 days following publication of this final rule.

Incorporation by Reference Date: The incorporation by reference of publications listed in this final rule has been approved by the Director of the Federal Register as of October 1, 2002.

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I. Background

On January 22, 2001, the Research and Special Programs Administration (RSPA, we) published a notice of proposed rulemaking (NPRM; 66 FR 6941) to revise the current requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of infectious substances, including regulated medical waste. The NPRM also proposed new requirements applicable to the transportation of genetically modified micro-organisms. The NPRM proposed the following changes to the HMR:

- Adoption of new classification criteria for infectious substances based on defining criteria developed by the World Health Organization (WHO) and consistent with standards contained in 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).
- 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. We proposed 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 Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA) regulations.
 - New transportation requirements for the transportation of genetically modified micro-organisms consistent with the UN Recommendations.

- New bulk packaging options for the transportation of regulated medical waste (RMW), based on current exemption provisions.

- New hazard communication requirements for shipments of Division 6.2 materials.

II. Comment Summary

We received 46 comments on the NPRM from industry associations, laboratories, medical waste transporters, state departments of transportation and public health, a blood bank, and private citizens. Most were supportive of our effort to harmonize the HMR requirements applicable to the transportation of infectious substances with international requirements, and of proposals to enhance the safe transportation of diagnostic specimens and biological products. Based on comments received and our discussions with other Federal agencies responsible for regulating infectious substances and genetically modified micro-organisms, this final rule incorporates the following changes to the HMR:

- New classification criteria for infectious substances based on defining criteria developed by WHO and consistent with standards contained in the UN Recommendations and the ICAO Technical Instructions.
- Revised packaging requirements for Division 6.2 materials consistent with international performance standards.
- Revised materials of trade exceptions to include certain diagnostic specimens, biological products, and RMW. This final rule includes more specific packaging requirements for such materials of trade than were proposed in the NPRM.
 - New packaging and hazard communication requirements for shipments of diagnostic specimens consistent with international requirements. Diagnostic specimens transported in dedicated motor vehicles by private or contract carriers are excepted from most requirements of the HMR. This final rule also clarifies that diagnostic specimens that contain a Risk Group 1 pathogen, do not contain a pathogen, or in which the pathogen is neutralized or inactive, are not subject to HMR requirements.
 - Modification of the current exception from requirements in the HMR for biological products. This final rule revises the proposal in the NPRM to specify that the exception is limited to biological products, including experimental products, subject to Federal approval, permit, or licensing requirements, such as those required by FDA or USDA.

- New bulk packaging options for the transportation of RMW, based on current exemption provisions. The packaging options proposed in the NPRM are modified in this final rule to reflect commenters' concerns about specifications for the packagings.

- New hazard communication requirements for bulk shipments of RMW to assist emergency responders to identify such shipments.

In discussions during development of this final rule, several federal agencies involved in the regulation of genetically modified organisms (*i.e.*, the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA)) commented that the process of genetically modifying an organism does not *a priori* make that organism a hazard. Rather, the product of the modification must be evaluated for potential risk. As several federal agencies currently regulate genetically modified organisms, the proposals in the NPRM concerning genetically modified organisms are not adopted in this final rule.

Comments we received in response to the NPRM are discussed in detail below.

A. Pending Revisions to the UN Recommendations

Most commenters support our proposal to harmonize the HMR requirements for infectious substances with the international standards. Two commenters note the United Nations may be developing a complete revision to its current recommendations for the transportation of infectious substances. According to these commenters, the UN may change the WHO risk group system as applied to transportation and may "radically" simplify current transportation requirements. These commenters advise us to postpone revising the HMR until the United Nations completes its work.

The commenters are correct. The UN Committee of Experts on the Transport of Dangerous Goods is considering revisions to the requirements in the UN Recommendations applicable to the transport of infectious substances and genetically modified micro-organisms. However, it is not certain whether any amendment will be adopted during the 2001–2002 biennium. Indeed, as yet the UN Committee of Experts has not received a formal proposal. Given this uncertainty, we do not agree with delaying action to harmonize the HMR requirements for infectious substances with current international standards. If the UN Committee of Experts adopts revisions to the UN Recommendations for transporting infectious substances,

we will consider such revisions in a future rulemaking.

One commenter notes the proposal as it relates to diagnostic specimens is not consistent with current requirements for transporting diagnostic specimens in the ICAO Technical Instructions. This is true; as we noted in the January 2001 NPRM, the proposal for shipping diagnostic specimens is consistent with a proposal for the UN Recommendations, since adopted. Since publication of the NPRM, the ICAO Dangerous Goods Panel has also adopted these amendments. As a result, the 2003–2004 edition of the ICAO Technical Instructions will be consistent with the UN Recommendations and this final rule.

B. Infectious Substance Definition

In the NPRM, consistent with current requirements in the UN Recommendations, we proposed to define infectious substances, or Division 6.2 materials, to mean materials known to contain or suspected to contain a pathogen with the potential to cause disease upon exposure. We further proposed to require Division 6.2 materials to be assigned to risk groups using defining criteria developed by WHO. WHO defines four risk groups for infectious substances based on pathogenicity, mode and ease of transmission, degree of risk to individuals and communities, and reversibility of the disease through known and effective preventative agents and treatment. Risk Group 1 includes micro-organisms unlikely to cause human or animal disease. In the NPRM, we proposed that Risk Group 1 materials not be subject to regulation under the HMR.

Several commenters oppose using the WHO risk group criteria for infectious substances regulated under the HMR. They note that the WHO system was intended for assessing and addressing risks to researchers and health care workers in laboratory environments, not for transportation. We do not agree. While it is true the WHO risk groups were not originally intended for transportation environments, they do provide a relatively simple way to delineate and differentiate risks associated with specific pathogens. As such, the WHO risk groups are a useful tool for assessing the degree to which specific pathogens should be regulated in transportation, based on the potential risk to transportation workers and the general public. Other risk systems (for example, the biosafety level guidelines in the Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) publication *Biosafety in*

Microbiological and Biomedical Laboratories) were also developed for use in laboratories rather than in transportation. These systems can be more difficult to apply for transportation purposes than the WHO risk groups.

Some commenters opposed to the use of the WHO risk groups recommend we create an advisory group to assign risk group classifications for infectious substances in transportation. We do not believe this is a practical or feasible approach because of the length of time that would be involved in establishing the advisory group and awaiting the results of its deliberations. Other commenters opposed to use of the WHO risk groups suggest we adopt government or industry consensus standards for risk group assignments, such as those developed by NIH. The NIH and WHO lists are very similar; NIH has published specific names of micro-organisms assigned to each risk group in a table. Although not complete, the NIH list is a useful reference source for identifying the appropriate risk group for a given pathogen. (The NIH guidelines can be found at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>). There are other risk group listings that also provide useful guidance for assigning a specific pathogen to a risk group, including a list developed by the American Biological Safety Association (available on line at <http://www.absa.org/riskgroups/index.htm>) and the list of agents in the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (available on line at <http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>). We do not agree the HMR should incorporate one or more of these lists by reference into the HMR. However, in this final rule we are including these lists in the table of informational materials in § 171.7(b).

Instead of the WHO risk groups, one commenter suggests we utilize the existing Packing Group system in the HMR to address differing risks associated with the transportation of specific infectious substances. Thus, the commenter suggests Packing Group I would contain virulent pathogens that have a high risk of airborne infection, readily penetrate unbroken skin, are extremely persistent in the environment, and for which effective preventative or treatment measures are not readily available. Packing Group II would contain pathogens with a significantly lower risk of airborne infection, the primary exposure risk of which is entry through broken skin or contact with mucous membranes, and for which effective preventative or

treatment measures are readily available. Packing Group III would contain pathogens classed as WHO Risk Group 2 materials.

We do not agree the existing Packing Group system provides a viable alternative to the WHO risk groups. As set forth in the NPRM, the WHO risk groups are used to identify pathogens not subject to regulation (Risk Group 1) or to identify certain pathogens (Risk Group 2 and 3) that may be shipped under certain exceptions, such as materials of trade. Unless an exception is authorized, all Risk Group 2, 3, and 4 infectious substances must be transported in specification triple packagings authorized under the HMR. In addition, they must be marked and labeled in accordance with applicable requirements, and accompanied by appropriate shipping and emergency response documentation. The packing group system suggested by the commenter would require shippers to distinguish between Risk Group 2 and 3 infectious substances when making packaging decisions, and would be more difficult, confusing, and burdensome to implement than the system proposed in the NPRM.

The NPRM proposed to assign infectious substances to risk groups 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. One commenter suggests this provision could endanger patient confidentiality and violate medical privacy regulations. We disagree. The proposal does not require health care professionals to disclose medical histories or patient symptoms. Rather, the proposal suggests these factors should be considered as the health care professional assigns an infectious substance to a risk group for purposes of transportation. Disclosure of the factors contributing to this determination or the name of the patient is not required. Further, the requirement for inclusion of an itemized list of contents within a package containing Division 6.2 materials requires a shipper only to identify the material. There is no requirement to include a patient name on the itemized list.

One commenter suggests we modify the list of factors used to determine risk group assignments to include the type of test ordered on the specimen. We do not believe it is necessary to specify this information as a factor in making risk group determinations. Shippers should make risk group assignments based, in part, on professional judgement concerning the individual

circumstances of the patient or animal. Such professional judgement should include the types of tests ordered or other factors.

One commenter recommends we regulate infectious substances meeting the defining criteria for a Risk Group 1 material for transportation purposes. We disagree. By definition, Risk Group 1 infectious substances are micro-organisms unlikely to cause human or animal disease. Risk Group 1 infectious substances in transportation pose little or no risk to transportation workers or to the general public. Risk Group 1 infectious substances are not subject to regulation under international transportation requirements because the risk posed by such materials is very low. There is no compelling safety rationale for regulating such materials under the HMR.

A number of commenters suggest specific revisions to the proposed definition of infectious substances. For example, several recommend including prions in the definition. Prions are not micro-organisms, but are proteinaceous infectious particles consisting of an abnormal isoform of a normal cellular protein. Prions are implicated as a cause for neuro-degenerative diseases such as kuru and Creutzfeldt-Jacob disease in humans, and bovine spongiform encephalopathy and scrapie in animals. We agree with commenters that a strict reading of the proposed definition in the NPRM would appear to exclude prions; therefore, we have modified the definition to specifically include them. We further revised the definition for clarity and to remove superfluous or inaccurate terminology.

One commenter suggests limiting regulation of infectious substances in transportation to those capable of infecting "immunocompetent humans and animals." For purposes of the HMR, "immunocompetent" would mean the human or animal possesses an effective body immune mechanism with no reduced immunity to infection by any known cause. We disagree. The WHO risk group system assigns infectious substances to risk groups based on their ability to infect immunocompetent humans and animals. Thus, it is not necessary to make this explicit in the HMR.

Accordingly, in this final rule we are defining Division 6.2 materials using the WHO risk group criteria. Division 6.2 materials must 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. Assignments to risk groups are 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 are excepted from all HMR requirements, unless they meet the definition of another hazard class.

C. Packaging Requirements for Infectious Substances

In the NPRM, we proposed to incorporate several changes to the infectious substances regulations applicable to packaging requirements and performance tests. The changes were intended to make the HMR requirements consistent with the UN Recommendations and ICAO Technical Instructions. For example, we proposed to require manufacturers to meet UN marking requirements for packagings represented as conforming to the specifications for infectious substances packagings in the HMR. In addition, we proposed to require manufacturers to retain packaging design qualification records and to retest packagings every 24 months. Further, we proposed to replace the current requirement for a water immersion test with a water-spray test to simulate exposure to rainfall, as required by the ICAO Technical Instructions. Similarly, we proposed 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 package, if an equivalent level of performance is maintained. Commenters endorse these proposals. We are adopting them in this final rule without change.

One commenter suggests a more stringent packaging requirement for infectious substances. The commenter recommends we replace the current triple packaging requirement (water-tight primary receptacle, water-tight secondary packaging, and outer packaging) with a quintuple packaging. In the quintuple packaging, the primary receptacle is enclosed in a sealed plastic bag with absorbent material inside a watertight primary container inside a watertight secondary container inside a tertiary container or overpack. We disagree. The accident record demonstrates a triple packaging meeting the performance standard established in the HMR is sufficient to contain the material under normal conditions of transportation.

D. Exceptions for Domestic Shipments of Infectious Substances

In the NPRM, we proposed to expand the materials of trade (MOTS) exceptions currently permitted under § 173.6 of the HMR. The proposal expanded the MOTS exception to include certain biological products, diagnostic specimens, and RMW, including cultures and stocks. MOTS 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 MOTS exception limits the maximum gross weight of MOTS that may be carried on a motor vehicle and includes minimum packaging and hazard communication requirements. As proposed in the NPRM, the MOTS exception for infectious substances specified combination packagings, with limitations on capacity.

A number of commenters address the proposed MOTS exception for infectious substances. Several commenters oppose the exception, suggesting it is too broad and does not provide adequate packaging or hazard communication. Other commenters support the exception, but recommend we incorporate minimal acceptable standards for packaging. These commenters note that most items shipped under the MOTS exception must be shipped in their original packaging or the equivalent. However, biological products, diagnostic specimens, and RMW are packaged for the first time when they are collected at the site from which they will be shipped. Thus, these commenters suggest the inner packaging should be puncture- and leak-resistant and there should be sufficient absorbent material for the contents of the inner packaging.

We agree with commenters that the MOTS exception for Division 6.2 materials should include general packaging standards. Therefore, in this final rule, we are adding performance requirements for combination packagings authorized under the MOTS exception for transportation of Division 6.2 materials. The inner packaging of the combination packaging must be leak tight for liquids, and the outer packaging must contain absorbent material sufficient to absorb the entire contents of the inner packagings. For sharps, which are objects that can pierce certain types of packaging, the inner packaging of the combination packaging must be constructed of a rigid, puncture-resistant material. For all Division 6.2 materials, the outer

packaging must be a strong, tight packaging that is securely sealed. Note that Division 6.2 materials shipped in conformance with the MOTS exception are subject to all applicable requirements in § 173.6. This includes requirements to mark packages with a common name or proper shipping name, and to inform the motor vehicle operator of the presence of a hazardous material and the requirements of § 173.6.

A commenter asks us to clarify the MOTS exception for RMW, with respect to home health care providers. Specifically, this commenter believes the NPRM was confusing in its treatment of waste generated from households. The commenter states the NPRM proposed the MOTS exception in § 173.6 as appropriate for home health care providers. At the same time, the NPRM provided a complete exception in § 173.134 from HMR requirements for medical waste generated from households and transported in accordance with applicable state or local requirements. The exception for medical waste generated from households applies to waste collected by local sanitation workers along with trash, garbage, and other non-medical household waste. The MOTS exception applies to RMW generated through home treatment of medical conditions by professional health care providers. These health care providers remove such waste and transport it elsewhere for disposal.

One commenter recommends the HMR include an exception from all transportation regulatory requirements, except for minimal packaging standards, for Risk Group 2 materials transported by highway. The commenter did not provide a reason for this recommendation. We disagree. Risk Group 2 infectious substances can pose risks to transportation workers and the general public. We believe they should be regulated in the same manner as Risk Group 3 infectious substances.

One commenter suggests the final rule should include an exception for environmental microbiological samples collected in the field to evaluate occupational and residential exposure risks. An example is a piece of moldy wallboard. The organisms in such samples are predominantly from the environment rather than humans, and therefore pose a limited risk of infection to the individual or the community. We agree and so modified the list of materials excepted from the HMR to include environmental microbiological samples being transported for analysis and/or testing. Note, however, that a material or object known or suspected to

be contaminated with an infectious substance must be transported in accordance with all applicable HMR requirements.

The same commenter also expresses a concern about the effect of the proposals in the NPRM on samples shipped to laboratories to evaluate their proficiency in analyzing and identifying pathogens and other materials. The commenter is concerned the NPRM would require such samples to be identified in shipping documentation or on labels. In fact, this is not the case. The HMR requires the technical name of an infectious substance to be shown in parentheses as part of the basic shipping description on shipping papers and package markings. However, the definition of "technical name" in § 171.8 of the HMR permits use of a generic description in place of the technical name for proficiency testing. Thus, an infectious substance sample sent to a laboratory for proficiency testing may show a generic microbiological description, such as bacteria, mycobacteria, fungus, or viral sample, as part of the shipping description. Packaging, marking, and labeling the proficiency testing sample as an infectious substance and using a generic technical name should not compromise proficiency testing programs.

E. Diagnostic Specimens

In the NPRM, we proposed regulations applicable to the transportation of diagnostic specimens consistent with the UN Recommendations. Diagnostic specimens are human or animal material being transported for diagnostic or investigational purposes. We proposed a new entry in the Hazardous Materials Table—"Diagnostic Specimen." We did not propose a UN number, warning label, or packing group assignment.

As proposed in the NPRM, diagnostic specimens meeting the definition of a Risk Group 4 material would be classed and required to be transported as Division 6.2 materials, UN 2814 or UN 2900. All other diagnostic specimens would be packaged in non-specification packagings meeting minimum performance criteria. Under the proposal, packages containing diagnostic specimens would be required to be marked "Diagnostic Specimens." Diagnostic specimens shipped in accordance with these provisions would be excepted from all other HMR requirements, except for incident reporting for diagnostic specimens transported by aircraft.

Several commenters oppose the NPRM proposal for diagnostic specimens. These commenters suggest that requirements for the shipment of diagnostic specimens should be applied based on whether a specimen could reasonably be suspected of being infectious. According to these commenters, any shipments other than routine screening samples or samples transported to investigate non-communicable diseases or conditions should be fully regulated as Division 6.2 materials. As we noted in the NPRM (66 FR 6944), we issued an ANPRM under this docket (63 FR 46844; September 2, 1998) proposing a regulatory regime for diagnostic specimens similar to this commenter's suggestion. Commenters to the ANPRM almost unanimously opposed this approach, stating it would be difficult and costly to implement. Commenters to the ANPRM also stated such a requirement could result in shipment delays. This would make early detection and treatment of disease difficult, and could significantly increase health care costs. We agreed. The NPRM proposal specifies a more practical, cost-effective, and easy-to-understand regulatory system for diagnostic specimens, consistent with requirements established in the UN Recommendations.

A number of commenters suggest the table entry for diagnostic specimens is ambiguous and may cause confusion. The table entry indicates that diagnostic specimens are regulated as hazardous materials. However, the specific provisions proposed for transportation of diagnostic specimens except such shipments from most requirements applicable to hazardous materials. Several commenters recommend we remove the entry from the table, to clarify that diagnostic specimens are not regulated as hazardous materials.

We disagree. In fact, the NPRM proposed a table entry for diagnostic specimens precisely to indicate diagnostic specimens would be regulated as hazardous materials under the HMR. There are a number of materials listed in the table as hazardous materials that are excepted from most HMR requirements, as we proposed to do for diagnostic specimens. For example, lithium batteries are regulated for transportation purposes as a hazardous material and are listed in the table, but are excepted from many requirements of the HMR when shipped in accordance with the provisions in § 173.185.

One commenter notes that diagnostic specimens are usually shipped with a transport media. The transport media preserves the specimen, prevents

overgrowth, and facilitates isolation and analysis. This transport media may inactivate or disable any pathogens contained in the specimen. The commenter states that the NPRM overlooks this aspect of diagnostic specimens shipments, exaggerating the risk associated with transportation. Other commenters agree and suggest the final rule should clarify that if no pathogen is present in the diagnostic specimen or if the pathogen is neutralized, then the specimen is not regulated under the HMR. We agree. In this final rule, we added diagnostic specimens in which no pathogen is present or the pathogen is neutralized to the list of materials not subject to regulation as infectious substances under the HMR. Note, however, that a transport media used in the shipment of infectious substances may itself be a hazardous material—i.e., it meets the definition of one of the defined hazard classes based on flammability, corrosivity, toxicity, or other hazard characteristic. If so, the shipment must be transported in accordance with HMR requirements for the specific hazard class. Note, also, that a diagnostic specimen shipped in a packaging with a neutralizing agent designed to function only if the inside packaging containing the diagnostic specimen ruptures or breaks, must be shipped in accordance with the requirements applicable to diagnostic specimens in § 173.199.

Several commenters suggest the regulations should take into account the physical nature of a diagnostic specimen when prescribing packaging requirements. For example, commenters state certain diagnostic samples, such as dried blood spots, fecal smears, and skin punches, do not present the same risks in transportation as liquid or semi-solid diagnostic samples. Similarly, commenters state urine and oral tissues are incapable of transmitting disease in the same manner as blood. These commenters recommend modification of the regulations to distinguish between diagnostic specimens that pose a threat of infection to transport workers and the general public, and those that do not. We disagree. Solid-form diagnostic specimens potentially containing infectious substances do present a risk of infection, as do urine and oral tissues. Although this risk may be less than for blood, we believe the minimal packaging standards for the transportation of diagnostic specimens should apply consistently to all materials meeting the definition of a diagnostic specimen in this final rule. Moreover, the packaging standards

established in this final rule do distinguish between solid- and liquid-form diagnostic specimens. For example, the capacity limits for liquid diagnostic specimens are less. Further, liquid diagnostic specimen packagings transported by aircraft must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Several commenters address the specific packaging requirements proposed for the transportation of diagnostic specimens. The NPRM proposed to require diagnostic specimens to be packaged in primary receptacles packed inside secondary packaging, secured in an outer packaging with suitable cushioning material. One commenter states there is no need to secure the secondary packaging inside the outer packaging, because the specimen is twice contained in leak-proof, watertight packaging with absorbent material in between. This commenter asserts the proposal adds to overall packaging costs with no transportation safety benefit. We disagree. The requirement to secure secondary packaging inside the outer packaging helps assure the integrity of the entire packaging, by preventing damage to the secondary packaging resulting from handling during transportation. Moreover, the requirement is consistent with international standards. Further, secondary packaging can be secured inside an outer packaging in several ways that do not necessarily involve tying or fastening the secondary packaging to the outer packaging. For example, if the secondary packaging fits snugly within the outer packaging, the secondary packaging would be considered to be secured within the outer packaging.

In addition, several commenters state the proposed capacity limits on packages of diagnostic specimens should be more flexible to accommodate dry ice for preservation of specimens. The NPRM proposed an outer packaging capacity limit of 4L (1 gallon) for liquid diagnostic specimens, and 4 kg (8.8 pounds) for solid diagnostic specimens. These capacity limits apply to the diagnostic specimen only; packagings may be larger to accommodate dry ice used for preservation of specimens. Note, however, that shipments using dry ice are subject to applicable requirements in § 173.217.

Another commenter suggests the packaging requirements for diagnostic specimens should be more stringent than in the NPRM. This commenter recommends a quintuple packaging, consisting of a primary receptacle

enclosed in a sealed plastic bag contained in a primary container, inside a secondary container, inside a tertiary container. We disagree. The packaging for diagnostic specimens proposed in the NPRM is consistent with packaging requirements in the UN Recommendations. Further, the packaging suggested by the commenter would add significantly to the cost of shipping diagnostic specimens.

One commenter addresses the "diagnostic specimen" marking requirement proposed in the NPRM. This commenter states the proposed marking requirement is redundant and provides no transportation benefit. We disagree. Under the proposal in the NPRM, packages containing diagnostic specimens must be marked "Diagnostic Specimen." No other marking or labeling is required, nor are shipping papers required; thus, it is difficult to see how the proposed marking could be "redundant." The marking is intended to communicate a potential hazard to transportation workers. Diagnostic specimens shipped in accordance with the provisions in the NPRM could contain infectious material, and the marking indicates transportation workers should take appropriate precautions if the package is damaged or leaking.

Another commenter suggests we adopt and modify the "Excepted Quantities Label" authorized by International Air Transport Association (IATA) standards, to indicate a shipment contains a diagnostic specimen. We believe the marking requirement in this final rule accomplishes the same goal without the additional regulatory burden that would result from a new labeling requirement. However, this final rule does not prohibit shippers from voluntarily applying the "Excepted Quantities Label" to such packages in addition to the "Diagnostic Specimen" marking.

In addition to the MOTS exception previously discussed, the NPRM also proposed a complete exception from the HMR for diagnostic specimens transported by private or contract motor carriers. One commenter opposes this exception, out of concern that inadequate packaging would expose untrained emergency response personnel to potentially infectious materials. However, most commenters generally are supportive of this proposal, agreeing the packaging and procedures used for courier shipments of diagnostic specimens are sufficient to assure the safety of such shipments in transportation. Further, couriers are familiar with the materials they transport, and are trained in the

application of the Occupational Safety and Health Administration (OSHA) standards for Universal Precautions for handling materials potentially containing infectious substances. Therefore, this exception is adopted as proposed in this final rule.

The NPRM proposed to except diagnostic specimens prepared in accordance with proposed § 173.199 from training requirements in Subpart H of Part 172 of the HMR. In lieu of training, the NPRM proposed to require offerors and transporters of diagnostic specimens to be informed of the diagnostic specimen packaging requirements. Commenters did not specifically address this aspect of the proposed requirements for diagnostic specimens in the NPRM. One commenter asked us to clarify the meaning of "must be informed" as used in proposed § 173.199.

As used in new § 173.199 of this final rule, "must be informed" means persons who offer or transport diagnostic specimens for transportation in accordance with § 173.199 must know about and be able to apply the requirements of § 173.199 to specific shipments. There are no record-keeping or certification requirements associated with this provision, which distinguishes this requirement as a less formal type of training requirement than would otherwise be required by subpart H of part 172. In this final rule, we modified the NPRM proposal to indicate persons who ship or transport diagnostic specimens must know about the provisions in § 173.199.

The NPRM proposed to subject diagnostic specimens transported by aircraft to incident reporting requirements. Several commenters oppose this proposal. They suggest an incident-reporting requirement may cause air carriers to refuse shipments of diagnostic specimens, which could lead to serious delays in the testing process and adversely affect the provision of quality health care to patients. We disagree that the incident reporting requirement should be removed from this final rule. Commenters' suggestion that air carriers may refuse shipments as a result of this requirement is speculative; no air carriers indicated they would refuse shipments as a result of this provision. Further, we believe the benefits of incident reporting will be significant. Since diagnostic specimens are currently excepted from all regulatory requirements in the HMR, we currently have only anecdotal information concerning incidents involving diagnostic specimens. Information provided through incident reports will allow us to more fully

evaluate the risks posed by these materials in transportation and to assess the efficacy of the packaging requirements imposed by this final rule.

One commenter suggests air carriers may not be able to identify a leak as coming from a package containing a diagnostic specimen. Since the package must be marked with the words "Diagnostic Specimen," we do not believe such identification will be difficult.

Two commenters suggest the proposed requirements for transporting diagnostic specimens will be "prohibitively expensive" for the industry. However, these commenters do not provide supporting evidence for this assertion. We disagree. The provisions for air shipment of diagnostic specimens are consistent with the UN Recommendations and will be consistent with the 2003–2004 Edition of the ICAO Technical Instructions, which most air carriers follow for both domestic and international transportation. Further, the final rule includes several exceptions for ground transportation of diagnostic specimens, thus minimizing new costs for health care providers.

Accordingly, this final rule adopts the provisions applicable to the transportation of diagnostic specimens proposed in the NPRM. Diagnostic specimens meeting the definition of a Risk Group 4 material must be classed and transported as Division 6.2 materials, UN 2814 or UN 2900. Diagnostic specimens known or suspected to contain a Risk Group 2 or 3 infectious substance must be packaged in primary receptacles packed inside secondary packaging to preclude breakage, punctures, or leakage. For liquids, there must be 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 Specimen." Diagnostic specimens shipped in conformance with these provisions are excepted from all other requirements in the HMR, with one exception. Diagnostic specimens transported on board aircraft are subject to the incident reporting requirements in §§ 171.15 and 171.16. Under this

final rule, offerors and transporters of diagnostic specimens must know about the diagnostic specimen packaging requirements. A commenter asked if diagnostic specimens shipped in conformance with these provisions would be subject to HMR requirements for notification-of-pilot-in-command. The answer is no.

We note that waste diagnostic specimens—diagnostic specimens meeting the definition for RMW in this final rule—may not be transported under the exceptions established in this final rule for the transportation of diagnostic specimens. Waste diagnostic specimens lose their identity as diagnostic specimens for purposes of the HMR, and must be transported in accordance with the HMR requirements applicable to RMW.

F. Biological Products

Commenters to the NPRM generally support its proposals concerning transportation of biological products. Currently, biological products are excepted from the HMR provided they meet FDA or USDA regulations governing the transfer of biological products. In the January 2001 NPRM, we proposed to limit this exception to biological products meeting the definition of a Risk Group 1 material or licensed for use under current FDA or USDA regulations. We proposed 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 proposed to add a special provision in § 172.102 relating to the transportation of blood and blood products. For consistency with ICAO Technical Instruction Special Provision A81, this special provision would except blood and blood products from current quantity limits for shipments by air when the materials are packaged in primary receptacles not exceeding 500 mL (17 ounces) and contained in outer packagings not exceeding 4 L (1 gallon).

We also proposed to except from all HMR requirements the following: 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.

A number of commenters note that veterinary biological products are regulated by USDA, regardless of their licensing status. Such veterinary biological products are subject to comprehensive regulation (9 CFR Parts

101 through 124). For example, veterinary biological products in pre-license status are regulated by USDA under 9 CFR 103.3 and are shipped only after USDA review and approval. The USDA requirements are designed to assure that the biological materials are not contaminated during shipment and pose no threat to agriculture or livestock. Similarly, under the Virus-Serum-Toxic Act of 1913 (21 U.S.C. 151 *et seq.*), imported veterinary biological products are subject to permit rather than licensing requirements. USDA regulations assure that imported veterinary biological products meet the same high standards for distribution and sale in the United States as domestically produced biological products. Based on USDA's comprehensive regulatory scheme, commenters recommend that imported veterinary biological products subject to USDA permitting procedures be excepted from HMR requirements. We agree biological products subject to USDA regulation should be excepted from HMR requirements, and have modified the list of exceptions in this final rule accordingly.

A commenter recommends we expand the exception from regulation for biological products subject to Federal approval and licensing requirements, to include products manufactured by facilities licensed by or registered with a Federal agency. We disagree. The current exception is product-specific because Federal requirements for approval and licensing of biological products assure their safety. Products manufactured by licensed or registered facilities may or may not be subject to Federal approval processes and so may or may not have a record demonstrating their safety.

One commenter disagrees with the proposed exception in the NPRM for blood collected for transfusions. The commenter states all human blood should be treated as infectious material. If not, transport workers would be subject to less stringent protective requirements than laboratory and hospital workers. We disagree. Blood collection facilities are subject to the OSHA regulations for handling potentially infectious blood and blood products (29 1910.1030). The OSHA regulations include requirements for handling, packaging, and shipping blood. Because blood collection facilities are subject to OSHA regulations, we believe an exception from the HMR for blood collected for transfusion is justified.

One commenter suggests the exception for blood collected for transfusion and blood products should be expanded to include blood and

plasma transported for testing as part of the donor process. We agree that blood sent for testing as part of the donor process should be excepted from regulation under the HMR. Therefore, we modified the proposal in the NPRM to except from the HMR blood sent for testing as part of the donor process, unless the person collecting the blood has reason to believe the sample contains an infectious substance. In such instances, the blood sent for testing must be packaged and shipped as a diagnostic specimen. Note also that blood and blood products transported for testing as part of the donor process is subject to OSHA requirements for handling and shipping.

Several commenters suggest the proposed exception from HMR requirements for blood collected for transfusion and blood products, organs, and tissues intended for transplant, should be expanded to include plasma derivatives. Plasma derivatives are derived from the same units of pre-screened blood used for transfusion. However, plasma derivatives are not "transfused." They are "infused." These commenters request clarifying the final rule to specify plasma derivatives are covered by the same exception as blood collected for transfusion. Plasma derivatives are covered under the exception for biological products in § 173.34(b) of this final rule. Therefore, no additional clarifying language is necessary.

A number of commenters note the proposed addition of Special Provision A81 does not reflect the most recent amendments to the UN Recommendations and the ICAO Technical Instructions. Effective June 20, 2001, the UN Recommendations and ICAO Technical Instructions include a Special Provision to except from aircraft quantity limits, body fluids packed in primary receptacles not exceeding 1,000 mL in outer packagings not exceeding 4 L. In this final rule, we revised Special Provision A81 for consistency with the most recent editions of the UN Recommendations and ICAO Technical Instructions. Thus, under this final rule, Special Provision A81 applies to shipments of any body fluid (*e.g.*, blood, plasma, urine, semen, saliva, spinal fluid, amniotic fluid, and the like).

One commenter recommends we expand the exception from HMR requirements for blood collected for transfusions or blood products, to include waste generated from the collection and testing of blood and blood products. We disagree. Waste is not packaged and transported with the same care as blood and blood products intended for transfusion, even under the

exception granted in this final rule. Further, waste generated from the collection of blood may include sharps and similar objects.

We note that all waste biological products—biological products meeting the definition for RMW in this final rule—may not be transported under the exceptions in this final rule 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.

G. Genetically Modified Micro-Organisms

In the NPRM, we proposed adding “Genetically modified micro-organism” to the Hazardous Materials Table as a Class 9 material. We proposed to require these materials to 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 also proposed two exceptions applicable to the transportation of genetically modified micro-organisms. First, we proposed 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 proposed 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.

A number of commenters address the proposals for genetically modified micro-organisms. Of major concern to the commenters is that the proposed requirements are not risk-based, but instead assume genetically modified micro-organisms pose a threat during transportation merely because of the fact that they are genetically modified. One commenter asserts the proposed Class 9 definition for genetically modified micro-organisms is scientifically meaningless, burdensome, and likely to impede essential research and development involving these materials. Other commenters are concerned that, as defined in the NPRM, genetically modified micro-organisms could include products enhanced through biotechnology. They fear that the requirement to transport genetically modified micro-organisms as Class 9 materials could be interpreted to apply to bulk shipments of biotechnology-enhanced agricultural commodities or products. Most commenters recommend

we regulate genetically modified micro-organisms only when they also meet the definition of an infectious substance.

We agree the NPRM proposals applicable to genetically modified micro-organisms may be unnecessarily broad, confusing, and difficult to apply and interpret. Further, there are a host of other stringent Federal requirements applicable to research, licensing, permitting, movement, and use of genetically modified micro-organisms. These regulatory systems were initially described in the policy statement referred to as “The Coordinated Framework” (51 FR 23302, June 26, 1986). For more specific details, please see the appropriate agency websites—for example, the EPA Biopesticides and Pollution Prevention Division at <http://www.epa.gov/pesticides/biopesticides/>; the EPA Office of Pollution Prevention and Toxics at <http://www.epa.gov/opptintr/biotech/index.html>; the Animal and Plant Health Inspection Service at <http://www.aphis.usda.gov>; and the FDA Center for Food Safety and Applied Nutrition at <http://vm.cfsan.fda.gov/list.html>.

Because a number of Federal regulatory agencies have rigorous programs in place to regulate the safety and distribution of genetically modified micro-organisms, and because the United States is engaged in ongoing international negotiations concerning global regulation of these materials, the proposals in the NPRM applicable to genetically modified micro-organisms are not adopted in this final rule. Note, however, that genetically modified micro-organisms meeting the definition of a Division 6.2 material are subject to regulation under the HMR.

H. Regulated Medical Waste

Commenters generally support the proposals in the NPRM to permit transportation of RMW in certain non-specification bulk packagings. However, commenters suggest several modifications to the proposals in the NPRM.

The NPRM defines “regulated medical waste” to mean waste or reusable material containing or suspected of containing an infectious substance in Risk Groups 2 or 3. RMW 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. RMW containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. One

commenter states the RMW definition is impossible to implement because generators of RMW will not know the specific materials contained in the waste. We disagree. Generators of RMW know the nature of the waste because of the materials they handle during the course of their operations. Further, Risk Group 4 materials are very closely regulated by the CDC, so a generator of RMW should know whether the waste contains a Risk Group 4 material.

One commenter recommends we require RMW containing Risk Group 1 infectious material to meet “minor” regulatory requirements. We disagree. As stated above, Risk Group 1 infectious substances are unlikely to cause human or animal disease, and so pose little or no risk to transportation workers or to the general public. There is no compelling safety rationale for regulating RMW containing only Risk Group 1 infectious material.

The NPRM proposed to authorize certain non-specification bulk containers for use as outer packagings for the transportation of RMW. Two commenters oppose this proposal out of concern that it represents a relaxation of current requirements for authorized RMW packagings to meet Packing Group II performance standards. We disagree. This final rule retains the Packing Group II performance requirements for non-bulk packagings. For bulk packagings, which are currently authorized under the terms of 29 exemptions, this final rule permits RMW to be transported in certain non-specification packagings with proven safety records gained through exemptions experience. These packagings have a demonstrated safety record. In addition, this final rule establishes performance standards for the authorized bulk packagings, including a requirement for certain packagings to be capable of passing a drop test at the Packing Group II performance level.

One commenter suggests the proposal would permit regulated medical waste to be transported in large, open-top, roll-off bulk containers. This is not the case. The non-specification bulk packagings authorized for the transportation of RMW must be closed with a lid or closure, to prevent intrusion of water into the packaging or release of contents from the packaging.

Several commenters suggest the provisions applicable to authorized bulk packagings are needlessly detailed. For example, commenters question the necessity of the proposed requirement for a wheeled cart (Cart) to be mounted on a minimum of four wheels and to have a gasketed lid. We agree. In this

final rule, we modified the bulk packaging provisions to provide for more flexibility in their design.

Other commenters suggest we should permit more flexibility for inner packagings inside bulk outer packagings. For example, one commenter notes that the 10-gallon limit on the size of sharps containers used as inner packagings, could preclude shipment of such items as specialized single-use drills, skin staple guns, and heart/lung machine and cell saver canisters, as RMW. We agree and modified this final rule accordingly. For sharps containers, this final rule requires a container with a capacity greater than 20 gallons to be capable of passing the performance tests in § 178.601 of the HMR at the Packing Group II performance level. A sharps container with a capacity of 20 gallons or less must be puncture resistant, but need not be capable of passing the Part 178 performance tests.

Commenters do not address our proposal to allow RMW to be transported in "Large Packagings," which are intermediate bulk packagings containing one or more inner packagings consistent with the requirements of the UN Recommendations. We adopted a definition for these packagings in a final rule issued under Docket HM-215D, published June 21, 2001 (66 FR 33316). The International Maritime Dangerous Goods Code also incorporates this definition. As defined 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 (7,000 liters, 793 gallons, or 106 cubic feet) in volume. The proposals in the NPRM concerning Large Packagings are adopted without change in this final rule.

One commenter raises concerns about the "certification" process for RMW packagings. The commenter suggests the "certification" standards are vague and assume manufacturing uniformity, which may or may not be present, according to the commenter. The commenter asserts "only the most sophisticated parties, that is, the larger transporters, have had containers certified" and this limits generators' flexibility in selecting the most appropriate, cost-effective packaging for transporting RMW. We disagree. Currently, the packaging standards in § 173.197 specify that non-bulk packagings for RMW must conform to the requirements of Part 178 at the Packing Group II performance level.

This means each packaging must be marked to certify the packaging conforms to all applicable requirements. The packaging design and manufacturing requirements apply to any manufacturer of a specification packaging, not just "the most sophisticated parties." Further, bulk packagings for transportation of RMW are currently authorized only under the terms of exemptions. The proposals in the NPRM in fact increase flexibility, and thus reduce costs for offerors and transporters of RMW by providing a range of bulk packaging options. These options include non-specification packaging options, not currently authorized under the HMR. We are adopting the NPRM proposals in this final rule.

The NPRM proposed to require inner packagings authorized for Large Packagings, Carts, and bulk outer packagings (BOP) to be marked or tagged with the name and location of the offeror. The proposal included an exception from these marking requirements when the entire contents of the Large Packaging, Cart, or BOP originate at a single facility and are delivered to a single location. One commenter opposes this exception. The commenter describes two incidents involving RMW found along public highways, presumably fallen from a transport vehicle. The bags within which the RMW was contained were not marked with the name and location of either the offeror or the consignee, and so could not be traced. The commenter suggests a lack of identification on inner packagings may exacerbate problems related to illegal dumping of RMW or poor package handling. We disagree. This exception is consistent with the current exception from marking for all hazardous materials shipments transported by highway without transfer from one motor carrier to another. This exception is also consistent with the current marking exception for shipments where the entire contents of a transport vehicle or freight container are shipped from one consignor to one consignee.

In response to a petition for rulemaking, the NPRM proposed to revise the HMR to permit transportation of Risk Group 2 or 3 waste cultures or stocks in non-specification packagings when transported by common or contract carriers in dedicated vehicles. Commenters did not specifically address this proposal. It is adopted as proposed in this final rule.

One commenter opposes the proposal in the NPRM to revise the quantity limitations applicable to shipments of RMW on aircraft. Currently, such

shipments are forbidden. We proposed 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 proposed to continue to prohibit bulk shipments of RMW on board aircraft. The commenter suggests RMW shipments are not time critical, and thus do not need to be transported by air, except in the rare instances already authorized by Special Provision A14. (Special Provision A14 permits air shipments of small quantities of RMW when other means of transportation are impracticable or unavailable.) We disagree. The proposals for transporting RMW on board aircraft are adopted in this final rule for consistency with the UN Recommendations and ICAO Technical Instructions. When properly packaged, non-bulk shipments of RMW may be safely transported by air.

One commenter notes many RMW generators depend on the entity transporting the RMW for many services related to the management of the waste. The commenter suggests the proposals applicable to RMW in the NPRM would require both generators and carriers to perform the same functions, greatly increasing the costs of compliance for generators. We disagree. A health care facility may contract with a waste hauler to perform all offeror functions associated with the transportation of its RMW. In this case, the waste hauler becomes the offeror of the RMW and is responsible for classifying the RMW, selecting appropriate packagings, assuring packagings are not overfilled, securing the closures on packagings, marking and labeling the packagings as appropriate, and generating shipping papers in accordance with the HMR. Workers in the health care facility who perform no offeror functions affecting the transportation safety of the shipment, but merely deposit medical waste in containers provided by the waste hauler, are not subject to HMR requirements. However, workers at a health care facility who perform offeror functions are subject to applicable requirements of the HMR. If a health care facility and a waste hauler split the performance of offeror functions, both the facility and the waste hauler are subject to the HMR as offerors.

In the NPRM, we noted in the preamble that waste diagnostic specimens and waste biological products—diagnostic specimens and biological products meeting the definition for RMW—could not be transported under the exceptions proposed in the NPRM for these

materials. One commenter opposes this distinction, stating that excepted products should continue to be excepted from HMR requirements when their status changes to waste. The commenter states regulating a material differently at various stages places an undue and unrealistic burden on medical staff in the field. We disagree. By definition, RMW is a waste or reusable material containing or suspected of containing a Risk Group 2 or 3 infectious substance. If a diagnostic specimen is found not to contain a pathogen, then it is not subject to regulation as RMW. Similarly, if an excepted biological product is not contaminated during use or handling with an infectious material, then it is not subject to regulation as RMW. Laboratory workers, health care providers, and medical staff should have no problem identifying those diagnostic specimens or biological products meeting the RMW definition, and transporting them with other RMW generated by the facility.

I. Used Health Care Products

In the NPRM we proposed to except from the HMR used health care products returned to the manufacturer, provided the products are shipped in a triple packaging conforming to certain manufacturing and marking requirements. The proposal required the primary and secondary containers to be marked with the OSHA BIOHAZARD symbol. In addition, we proposed to require the secondary container to be a watertight metal or plastic packaging designed and constructed in a manner to assure the used health care product and primary container remain intact during transportation. The NPRM proposed to require offerors and transporters of used health care products potentially contaminated with an infectious substance to be informed about the used health care product packaging requirements.

Several commenters address this proposal. Most suggest that the proposal is too broad. Further, commenters suggest that, for purposes of the HMR, the definition of used health care products should be limited to used products contaminated with potentially infectious body fluids or materials. Transportation requirements should apply only to products where the infectious hazards cannot be removed or mitigated prior to transportation. We agree and modified this final rule accordingly.

Commenters also suggest the packaging requirements for shipment of used health care products should be risk-based performance standards rather

than triple-pack specification standards, as proposed in the NPRM. We agree. Therefore, in this final rule we are revising the packaging requirements proposed in the NPRM to provide more flexibility for shippers.

Note that the person offering a used health care product for transportation under the HMR, not the original manufacturer of the product, is responsible for assuring compliance with the transportation requirements.

J. Hazard Communication

In the NPRM, we proposed to require bulk packagings containing RMW to be marked with the appropriate UN identification number and with a BIOHAZARD marking. The BIOHAZARD marking would have to conform to OSHA specifications for the BIOHAZARD marking in 29 CFR 1910.1030(g)(1)(i) to communicate to emergency response personnel the nature of the material being transported. We proposed to require the size of the BIOHAZARD marking to measure at least 273 mm (10.8 inches) on each side. Two commenters note many states require a 152.4 mm (6 inches) size marking, and ask us to consider changing our proposed size requirement. We agree and modified this final rule accordingly. In addition, the final rule includes a graphic representation of the BIOHAZARD symbol.

One commenter requests we allow a transition period for the new BIOHAZARD marking for bulk shipments of RMW, and for the marking requirements on inner packagings authorized for use inside bulk packagings authorized for the transportation of RMW. We agree. In this final rule we are specifying the effective date for both marking requirements as one year after the effective date of this final rule.

One commenter suggests all unique marking requirements for infectious substances, including regulated medical wastes, should be consolidated into one section in subpart D of part 172, rather than located in sections authorizing exceptions from certain requirements or in packaging authorization sections. We disagree. Placing some marking requirements with authorized exceptions or with packaging authorization requirements helps shippers easily identify all requirements with which they must comply when preparing packages for transportation.

Several commenters note certain packages of infectious substances may be subject to labeling requirements under both the HMR and the OSHA BIOHAZARD labeling requirements in

29 CFR 1910.1030. These commenters suggest we adopt a single labeling requirement, or we work cooperatively with OSHA to clarify that the OSHA BIOHAZARD label should not be used for transportation. While we agree with commenters that a dual labeling requirement for certain packages of infectious substances may be confusing, we determined that the OSHA BIOHAZARD label is not prohibited under § 172.401 of the HMR. We do permit use of the BIOHAZARD label in place of the INFECTIOUS SUBSTANCE label under certain conditions. However, substituting the BIOHAZARD label for the INFECTIOUS SUBSTANCE label in all cases is not feasible. The INFECTIOUS SUBSTANCE label is consistent with labels authorized by the UN Recommendations and the ICAO Technical Instructions for international shipments of infectious substances. We do work with OSHA to minimize regulatory duplications and inconsistencies and will continue to do so.

State, local, and tribal governments should be aware the Federal hazardous materials transportation law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*) contains an express preemption provision preempting state, local, and Indian tribe requirements on certain covered subjects (49 U.S.C. 5125(b)). 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.

The marking of a hazardous material for purposes of transportation in commerce 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 applicable to transportation in commerce 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). After August 14, 2003, non-Federal marking requirements applicable to hazardous materials transportation not substantively the same as the marking requirements for RMW included in this final rule are preempted, unless authorized by another Federal law or a waiver of preemption.

K. Training

Several commenters addressed training requirements associated with the regulation of infectious substances under the HMR. Currently, Subpart H of Part 172 requires a hazmat employer to assure each of its hazmat employees is trained, including general awareness/familiarization training, function-specific training, and safety training. A hazmat employee may not perform any function regulated under the HMR unless he or she is trained. One commenter states this level of training is infeasible and unnecessary for health care professionals, and suggests training should be more abbreviated and targeted to specific functions. This commenter further suggests we consider increasing the packaging integrity for shipments of infectious substances, in lieu of applying the hazmat employee training requirements to health care professionals.

We disagree that application of the training requirements to health care professionals is "infeasible" and "unnecessary." Training is essential to successful compliance with the HMR. Most health care professionals are already familiar with and trained in requirements that can be used to satisfy some training obligations under the HMR, such as the OSHA Universal Precautions procedures. Further, increased packaging integrity cannot be a substitute for training. Health care professionals need training to properly use any packaging authorized for the transportation of infectious substances, or the regulatory requirements would be meaningless. Moreover, for shipments conforming to requirements for materials of trade or diagnostic specimens in this final rule, the associated training requirements are minimal. They do not include the certification and record keeping provisions in subpart H of part 172.

Another commenter recommends we specify the level of training required for health care professionals, and other offerors and transporters of infectious substances. We disagree. Flexibility is built into the HMR training requirements, allowing hazmat employers to determine the method of training and the level to which each employee must be trained. This

flexibility helps to minimize the training burden on both hazmat employers and hazmat employees. This commenter also recommends we delay enforcement of the new requirements in this final rule to allow an appropriate period for retraining. Again, we disagree. This final rule is effective October 2, 2002; this should provide ample time to assure hazmat employees are trained in the new requirements.

L. Contaminated Food and Food Products

One commenter states that the definition of "infectious substance" in § 173.134, as proposed, could be read to require food and food ingredients tainted with salmonella to be shipped in accordance with requirements for transportation of infectious substances. Salmonella is listed in 42 CFR 72.3 as an infectious substance. This commenter notes salmonella-tainted food does not pose a significant, acute threat to transport workers or to the general public since it must normally be ingested to cause disease. This commenter suggests the final rule incorporate an exception from regulation for food and food ingredients tainted with salmonella or other bacteria. We agree. Indeed, there is no significant threat to life or property from the transportation of food, food ingredients, or food products contaminated with bacteria or other types of pathogens, particularly when such food is being transported as a result of a recall by the original processor. We modified the list of exceptions from HMR requirements in the final rule accordingly.

III. Section-by-Section Review

Part 171

Section 171.7

We are revising 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 are required for plastic inner packagings used to transport RMW inside Large Packagings and non-specification bulk packagings. We are also revising the table of informational material not requiring incorporation by reference. This revision will add three resources for shippers to use to assign a risk group to a specific infectious substance.

Section 171.8

We are adding definitions for "biological product," "cultures and stocks," "diagnostic specimen," "risk group," "sharps," and "toxin." These

definitions refer readers to the definitions in § 173.134 of the HMR.

Section 171.14

We are allowing a two-year transition period for the revised Division 6.2 labels adopted in this final rule.

Section 171.15

We are removing the term "etiologic agents" from paragraphs (a)(3) and (b) and replacing it with "infectious substances." In addition, in paragraph (b) we are adding 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 are removing the letter "D" in column (1). In column (7), we are removing the reference to Special Provision A14 and revising columns (9A) and (9B) to replace "Forbidden" with "No Limit" for quantity limitations on board aircraft. These 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 bulk packagings authorized for the transportation of RMW can be found in § 173.197 of the HMR. Finally, we are revising 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 are adding new special provisions in column (7). Special Provision A81 provides relief from quantity limits for the transport of body fluids containing infectious substances, when in primary receptacles not exceeding 1,000 mL (34 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.

In addition, we are adding 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 are also adding two new entries for "Toxins, extracted from living sources, liquid, n.o.s., UN 3172" and "Toxins, extracted from living sources, solid, 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 the materials are Division 6.1 materials, UN 3172, PG I, II, or III. We are adding Special Provision 141 to state that toxins containing infectious substances or 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 are revising this section by removing Special Provision A14, revising Special Provision A13, and adding Special Provisions 141, A81, and A82, as above detailed.

Section 172.323

We are adding this section to require bulk packagings containing RMW to be marked with a BIOHAZARD marking conforming to OSHA regulations at 29 CFR 1910.1030. In response to comments, this final rule requires the size of the marking to be at least 152.4 mm (6 inches) on each side. In this final rule, we are adding new paragraph (c) to require the BIOHAZARD marking to be displayed on a background of contrasting color. In addition, this final rule includes a graphic representation of the BIOHAZARD symbol.

Section 172.432

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

Section 172.502

We are revising paragraph (b) to indicate the restrictions on placarding in paragraph (a) of this section do not apply to the display of a BIOHAZARD marking on a white square-on-point background.

Part 173

Section 173.6

We are adding a MOTS exception for diagnostic specimens, biological products, and RMW, other than Risk Group 4 materials. The exception includes packaging requirements and quantity limitations. As suggested by commenters, this section incorporates minimum performance packaging standards for MOTS that are diagnostic specimens, biological products, or RMW.

Section 173.28

We are adding a requirement for Division 6.2 packagings to be disinfected prior to reuse. As suggested by a commenter, this requirement is

modified from the NPRM proposal to substitute the term “disinfect” for “decontaminate.”

Section 173.134

In paragraph (a), we are revising the definitions and classification criteria for “infectious substance,” “biological product,” “diagnostic specimen,” and “regulated medical waste;” and adding definitions for “cultures and stocks,” “risk group,” “sharps,” “toxin,” and “used health care product.”

We are revising 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. In response to comments, we revised the definition proposed in the NPRM for clarity and specificity.

We are revising 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 are defining “cultures and stocks” to mean a material prepared and maintained for growth and storage, and containing a Risk Group 2, 3, or 4 infectious substance.

We are revising 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 and described by the proper shipping name “Infectious Substance”. 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 are revising the definition for “regulated medical waste” to indicate regulated medical waste is a waste or reusable material containing or suspected to contain a Risk Group 2 or 3 infectious substance. 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 are adding a definition for “risk group” to mean a ranking of a micro-organism’s ability to cause injury through disease. For consistency with terminology used by other entities that use risk group definitions, in this final rule the definition is modified to

substitute “the severity of the disease caused by the organism” for “the pathogenicity of the organism” as proposed in the NPRM. Thus, risk group assignment criteria include: the severity of the disease caused by 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 are defining “sharps” to mean any object that may be contaminated with an infectious substance, and is able to cut or penetrate the skin or packaging material. The term includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. In response to comments, we have the definition proposed in the NPRM to include uncontaminated objects that may become contaminated during handling and transportation.

We are defining “toxin” to mean a Division 6.1 material obtained from a plant, animal, or bacterial source. The definition notes toxins containing an infectious substance or contained in an infectious substance, must be classed as Division 6.2 materials.

In paragraph (b), we are listing exceptions from the HMR requirements applicable to Division 6.2 materials. These exceptions include:

1. Biological products subject to Federal approval, permit, or licensing requirements.
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, including diagnostic specimens that do not contain a pathogen or in which the pathogen is inactivated or neutralized.
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.
9. Environmental microbiological samples collected to evaluate occupational and residential exposure risks.
10. Agricultural and food products.

In the NPRM, we proposed an exception from most HMR requirements for forensic material transported on behalf of the Federal government or a

state, local government, or tribal government agency, provided the material was shipped in a packaging conforming to the provisions of § 173.24. After the NPRM was published, we discussed this exception with officials from the Federal Bureau of Investigation (FBI). We were particularly concerned with shipments of forensic material associated with bioterrorism incidents. Based on our discussions with the FBI, this final rule modifies the exception proposed in the NPRM. This final rule requires forensic material known or suspected to contain a Risk Group 4 infectious substance or an infectious substance listed as a select agent in 42 CFR part 72 to be transported in packaging capable of meeting the HMR performance test standards for infectious substance packaging. In addition, the secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

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

In addition, we are revising the exception for laundry or medical equipment conforming to OSHA regulations in 29 CFR 1910.1030. This final rule clarifies 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 this final rule, we modified the exception for blood and blood products to add human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

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

Finally, we are adding paragraph (d) to clarify that if an item listed in paragraphs (b) or (c) of this section meets the definition of another hazard class, it must be offered for transportation and transported in accordance with applicable requirements of the HMR. Similarly, if an item listed in paragraphs (b) or (c) of this section 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 173.196

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

Section 173.197

We are revising this section to authorize certain bulk packagings for the transportation of RMW. Paragraph (a) includes general requirements for non-bulk and bulk packagings. Paragraph (b) requires non-bulk packagings to conform to the requirements of part 178 at the Packing Group II performance level. Paragraphs (c) and (d) authorize Large Packagings and non-specification bulk containers for the transportation of RMW. Paragraph (c) sets forth conditions governing the use of Large Packagings. Paragraph (d) sets forth the conditions governing the use of non-specification carts and bulk outer packagings. Paragraph (e) specifies the inner packagings authorized for use with bulk outer packagings.

Section 173.199

We are adding § 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, as appropriate. Generally, all other diagnostic specimens may be shipped in triple packagings capable of passing a 1.2 meter (3.9 feet) drop test.

Liquid diagnostic specimens must 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. The volumetric capacity of the outer packaging may not exceed 4 L (1 gallon).

Solid diagnostic specimens must 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).

Shipments of used health care products contaminated with an infectious substance and being returned to the manufacturer, must be transported in triple packagings 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. In response to comments, we revised this section to provide more packaging flexibility.

Diagnostic specimens and used health care products shipped in accordance with these provisions are not subject to most other requirements in the HMR. However, these shipments are subject to minimal training requirements. Further, diagnostic specimens are subject to incident reporting for shipments offered for transportation or transported by aircraft.

Part 177

Section 177.834

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

Section 177.843

We are adding paragraph (d) to require a transport vehicle to be disinfected prior to reuse if a Division 6.2 material is released from its packaging inside the vehicle. As suggested by a commenter, we modified this requirement to substitute the term “disinfect” for “decontaminate.”

Part 178

Section 178.503

We are adding paragraph (f) to incorporate markings for infectious substances packagings consistent with those in the ICAO Technical Instructions and the UN Recommendations.

Section 178.601

We are adding 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, manufacturers of infectious substances packagings are required to retain design qualification records in accordance with § 178.601(c)(1). In addition, we are adding a sentence to paragraph (c)(2) to indicate, 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 are adding a

sentence to paragraph (e) to require packagings used for transporting infectious substances to pass periodic retests.

Section 178.609

We are revising the section heading to remove the wording "(etiologic agents)." We are revising 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 are revising paragraph (e) to replace the current water immersion test with a water spray test to simulate exposure to rainfall consistent with the ICAO Technical Instructions. We are revising paragraphs (h)(1) and (h)(2) to clearly indicate that, during the penetration test, penetration of the primary receptacle is not acceptable. We are deleting current paragraph (i). We are adding 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.

IV. Coordination with Other Federal Agencies

In addition to RSPA, several Federal agencies have responsibility for regulating infectious substances. We provided CDC, USDA, FDA, EPA, and OSHA with copies of this final rule in advance of publication in the **Federal Register** for their information and comment. We asked them specifically to identify potential areas of conflict between their regulations and the provisions of this final rule. None of these agencies identified any potentially conflicting regulatory requirements.

V. Security Issues

As a result of the terrorist attacks of September 11, 2001, and subsequent threats related to biological materials, we are reviewing the HMR to determine if additional requirements are necessary to assure the security of hazardous materials in transportation. Certain infectious substances, including *Bacillus anthracis* (anthrax) and other materials listed as select agents by the CDC (42 CFR part 72), are materials that may pose a potential security risk. We initiated a project to address security issues related to infectious substances and other hazardous materials to determine if rulemaking action is necessary.

VI. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is considered a significant regulatory action under Executive Order 12866, and the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). A regulatory evaluation is available for review in the public docket.

The costs identified in the regulatory evaluation are minimal. They are primarily attributed to the regulation of shipments of diagnostic specimens containing a Risk Group 2, 3 or 4 pathogen and of new specification packaging requirements for infectious substances. Our estimate of costs is for a one-time initial cost of \$33,332, and a subsequent annual cost of \$28,351.

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 this final rule. Reported incidents to RSPA between 1990 and the present resulted in 2 minor injuries and \$3,281 in property damage. However, we believe that incidents are significantly under-reported.

Benefits resulting from implementation of this final rule include the following:

1. International harmonization.

Harmonization of requirements in the HMR with standards specified in the UN Recommendations, ICAO Technical Instructions, and IMDG Code will remove current inconsistencies among the regulations. This action will facilitate efficient transportation of infectious substances across national borders. More importantly, harmonized regulations reduce the potential for misunderstanding and confusion, enhancing 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 entire 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 potentially infectious diagnostic specimens and biological products should be

transported in authorized packaging. Further, such shipments should include communication of hazard to those who may come into contact with them. The HMIS data base and anecdotal information indicate packages of these currently excepted materials are sometimes damaged during transportation. This damage can result in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. The requirements in this final rule for more stringent packaging for these materials, combined with the exceptions for transportation of these materials as MOTS or by private or contract carriers in dedicated vehicles will assure swift and efficient transportation. This final rule will also reduce the risks to transportation workers and the general public. Enhancements to packaging 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 enhances overall safety while imposing insignificant costs on the regulated industry.

Although we cannot assign definitive dollar amounts to these potential benefits, we believe the final rule adopts the least costly alternatives available for ensuring an acceptable level of transportation safety, and the potential benefits to society exceed the potential costs associated with this final rule.

B. Executive Order 13132

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This final rule preempts state, local, and Indian tribe requirements, but does not propose any regulation with 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 that preempts state, local, and Indian tribe requirements on certain covered subjects (49 U.S.C. 5125(b)). 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 final rule addresses covered subject items 1–5 above and preempts state, local, and Indian tribe requirements not meeting the “substantively the same” standard. This final 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 § 5125(b)(2) that, if we issue a regulation concerning any of the covered subjects, we 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. The effective date of Federal preemption is one year from publication of this final rule in the **Federal Register**.

C. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (“Consultation and Coordination with Indian Tribal Governments”). This final rule does not have tribal implications, does not impose substantial direct compliance costs, and is not required by statute. Consequently, the funding and consultation requirements of Executive Order 13175 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 a rule is not expected to have a significant impact on a substantial number of small entities. Based on the assessment in the regulatory evaluation, I hereby certify that while this final rule applies to a substantial number of small entities, there will not be a significant economic impact on those small entities. 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 annual costs attributed to this final rule are minimal, especially when compared to 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.

E. Paperwork Reduction Act

RSPA has current information collection approvals under OMB No. 2137–0039, Hazardous Materials Incident Reports, which expires May 31, 2004, with 34,441 burden hours and \$825,621.66 annual costs; and OMB No. 2137–0557, Approvals for Hazardous Materials, which expires May 31, 2004, with 18,405 burden hours and \$415,237.40 annual costs. This final rule will result in small increases in annual burden hours and costs.

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 record keeping requests. The NPRM identified and requested comment on revised information collections submitted to OMB for approval. We estimated the total information collection and record keeping burden as proposed in the NPRM would be revised as follows:

OMB No. 2137–0039:

Number of Respondents: 1,536.

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 received no comments on these revised information collections. 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. OMB approved the revised information collections proposed in the NPRM on May 4, 2001, and May 9, 2001.

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

H. Environmental Assessment

We find there are no significant environmental impacts associated with this final rule. An environmental assessment is in the public docket for this rulemaking.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, 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 are amending 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 continues 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 are added in alphanumeric sequence under the American Society for Testing and

Materials, and three new entries are added in alphabetical order to the table in paragraph (b), to read as follows:

§ 171.7— Reference material.

(a) * * *

(3) Table of material incorporated by reference.

Table with 2 columns: Source and name of material, 49 CFR reference. Rows include American Society for Testing and Materials, ASTM D 1709-01, and ASTM D 1922-00a.

(b) List of informational materials not requiring incorporation by reference. * * *

Table with 2 columns: Source and name of material, 49 CFR reference. Rows include American Biological Safety Association, Centers for Disease Control and Prevention, and National Institutes of Health.

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

§ 171.8 Definitions 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.
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 is amended by adding paragraph (e) to read as follows:

§ 171.14 Transitional provisions for implementing certain requirements.

- (e) A Division 6.2 label conforming to specifications in § 172.432 of this subchapter in effect on September 30, 2002, may be used until October 1, 2005.
§ 171.15 [Amended]
5. In § 171.15, the following changes are made:
a. Paragraph (a)(3) is amended by removing the term "(etiologic agents)".
b. Paragraph (b) introductory text is amended by removing the term "etiologic agents" and in its place adding the term "infectious substances", and 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 continues to read as follows:

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

7. In § 172.101, the following proper shipping names are 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	Pas-senger aircraft/rail	Cargo aircraft only	Loca-tion	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[Add].												
	Diagnostic specimen	6.2				A82	134	199	None	4 L or 4kg.	4L or 4 kg.	A	40
G	Toxins, from living sources, liquid, n.o.s..	6.1	UN3172	I	6.1	141	None	201	243	1 L	30 L	B	40
				II		141	None	202	243	5 L	60 L	B	40
				III		141	153	203	241	60 L	220L	A	40
G	Toxins, from living sources, solid, n.o.s..	6.1	UN3172	I	6.1	141	None	211	243	5 kg	50 kg	B	
				II		141	None	212	243	25 kg	100 kg	B	
				III		141	153	213	241	100 kg	200 kg	A.	
	[Revise].												
G	Infectious substances, affecting animals <i>only</i> .	6.2	UN2900		6.2	A81, 82	134	196	None	50 mL or 50 g.	4 L or 4 kg.	B	40
G	Infectious substances, affecting humans.	6.2	UN2814		6.2	A81, 82	134	196	None	50 mL or 50 g.	4 L or 4 kg.	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 is added, and in paragraph (c)(2), Special Provision A13 is revised, Special provision A14 is removed, and Special Provisions A81 and A82 are added in alphanumeric order to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

Code/Special Provisions

* * * * *

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

* * * * *

(2) * * *

Code/Special Provisions

* * * * *

A13 Bulk packagings are not authorized for transportation by aircraft.

* * * * *

A81 The quantity limits in columns (9A) and (9B) do not apply to body fluids known to contain or suspected of containing an infectious substance when transported in primary receptacles not exceeding 1,000 mL (34 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. Section 172.323 is added to read as follows:

§ 172.323 Infectious substances.

(a) In addition to other requirements of this subpart, after September 30, 2003, 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 conforming 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 152.4 mm (6 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 152.4 mm (6 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.

(c) The background color for the BIOHAZARD marking required by paragraph (a) of this section must be orange and the symbol and letters must be black. Except for size the BIOHAZARD marking must appear as follows:



(d) The BIOHAZARD marking required by paragraph (a) of this section must be displayed on a background of contrasting color. It may be displayed on a plain white square-on-point

configuration having the same outside dimensions as a placard, as specified in § 172.519(c) of this part.

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

§ 172.432 INFECTIOUS SUBSTANCE label.

(a) * * *



* * * * *

11. In § 172.502, paragraph (b)(2) is revised to read as follows:

§ 172.502 Prohibited and permissive placarding.

* * * * *

(b) * * *

(2) The restrictions of paragraph (a) of this section do not apply to the display of a BIOHAZARD marking, a “HOT” marking, or an identification number on a white square-on-point configuration in accordance with §§ 172.323(c), 172.325(c), or 172.336(b) of this part, respectively.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

12. The authority citation for part 173 continues to read as follows:

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

13. In § 173.6, paragraph (a)(4) is redesignated as paragraph (a)(5), and a new paragraph (a)(4) is added to read as follows:

§ 173.6 Materials of trade exceptions.

* * * * *

(a) * * *

(4) 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. For liquids, the inner packaging must be leak tight, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging must be constructed of a rigid material resistant to punctures and

leaks. For all Division 6.2 materials, the outer packaging must be a strong, tight packaging securely closed and secured against movement.

(i) For a diagnostic specimen or biological product, combination packagings must conform to the following capacity limitations:

(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) For a regulated medical waste, a combination packaging must consist of one or more 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).

* * * * *

14. Section 173.28 is amended by adding paragraph (f) to read as follows:

§ 173.28 Reuse, reconditioning and remanufacture of packagings.

* * * * *

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

15. Section 173.134 is revised to read as follows:

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

(a) *Definitions and classification criteria.* For purposes 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. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause 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 a risk group 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. Infectious substances are subject to applicable requirements in 42 CFR Part 72—Interstate Shipment of Etiologic Agents.

(2) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. A *biological product* includes a material manufactured and distributed in accordance with one of the following provisions: 9 CFR part 102 (Licenses for Biological Products); 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR part 104 (Permits for Biological Products); 21 CFR part 312 (Investigational New Drug Application); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR parts 600 to 680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). A *biological product* known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material prepared and maintained for growth and storage and containing 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 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and 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 known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and 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, described as an infectious substance, and assigned to 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 severity of the disease caused by 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 contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. *Sharps* includes needles, syringes, 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 from a plant, animal, or bacterial source. A *toxin* containing an infectious substance or a *toxin* contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

(9) *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation.

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

(1) A biological product known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen.

(2) A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs.

(3) A biological product, including an experimental product or component of a product, subject to Federal approval, permit, 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.

(4) Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act.

(5) Blood collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as

part of the collection process, except where the person collecting the blood has reason to believe it contains an infectious substance, in which case the test sample must be shipped in accordance with § 173.199.

(6) 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 or contamination. 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.

(7) Laundry or medical equipment conforming 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 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 being transported for disposal.

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

(9) A living person.

(10) 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.

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

(12) Forensic material transported on behalf of a U.S. Government, state, local

or Indian tribal government agency, except that—

(i) Forensic material known or suspected to contain a Risk Group 2 or 3 infectious substance must be shipped in a packaging conforming to the provisions of § 173.24.

(ii) Forensic material known or suspected to contain a Risk Group 4 infectious substance listed as a select agent in 42 CFR Part 72 must be transported in packaging capable of meeting the test standards in § 178.609 of this subchapter. The secondary packaging must be marked with a BIOHAZARD symbol conforming to specifications in 29 CFR 1910.1030(g)(1)(i). An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(13) Environmental microbiological samples, such as a sample of dust from a ventilation system or mold from a wallboard, collected to evaluate occupational and residential exposure risks.

(14) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act.

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

(1) A regulated medical waste 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. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

(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.

16. Section 173.196 is 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 consisting of the following components:

(1) A watertight primary receptacle.
(2) A watertight secondary packaging. If multiple fragile 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 producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(7) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding without leakage temperatures in the range of -40°C to $+55^{\circ}\text{C}$ (-40°F to $+131^{\circ}\text{F}$).

(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 (freeze-dried) 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 must be provided, such as heat seal, skirted stopper, or metal crimp seal. 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(a) 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 containing or

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 meeting the requirements of § 173.197.

17. Section 173.197 is revised to read as follows:

§ 173.197 Regulated medical waste.

(a) *General provisions.* Non-bulk packagings, large packagings, and bulk outer packagings used for the transportation of regulated medical waste must be rigid containers meeting the provisions of subpart B of this part.

(b) *Non-bulk packagings.* Except as otherwise provided in § 173.134 of this subpart, non-bulk packagings for regulated medical waste must be DOT specification packagings conforming to the requirements of Part 178 of this subchapter at the Packing Group II performance level. A non-bulk 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) intended to be transported in the packagings.

(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 the waste is contained in inner packagings conforming to the requirements of paragraph (e) of this section. Each Large Packaging design 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.* Only 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 design intended for the transportation of sharps containers must be puncture resistant and capable of retaining liquids. The design must also be tested and certified as meeting 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) Regulated medical waste in each Cart or BOP must be contained in non-bulk inner packagings conforming to paragraph (e) of this section.

(ii) Each Cart or BOP must have smooth, non-porous interior surfaces free of cracks, crevices, and other defects that could damage plastic film inner packagings or impede disinfection 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 disinfected by any means effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated cultures and stocks of infectious substances containing 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 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 containing 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 conforming 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 with a nominal volume not exceeding 1,655 L (437 gallons).

(ii) Each Cart must be constructed of metal, rigid plastic, or fiberglass fitted with a lid to prevent 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 to prevent the intrusion of water (e.g., rain or snow).

(iii) Each opening in a BOP must be fitted with a closure to prevent 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 to 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 containing 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.* After September 30, 2003, 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 1709-01, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method* (see § 171.7 of this subchapter), and for impact resistance in ASTM D 1922-00a, *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method* (see § 171.7 of this subchapter). 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 transported in a Large Packaging, Cart, or BOP must be packaged in a rigid inner packaging conforming to the requirements of paragraph (a) of this section. Liquid materials are not authorized for transportation in inner packagings having a capacity greater than 19 L (5 gallons).

(3) *Sharps.* Sharps transported in a Large Packaging, Cart, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in § 178.601 of this subchapter at the Packing Group II performance level. A sharps container may be reused only if it conforms to the following criteria:

(i) The sharps container is specifically approved and certified by the U.S. Food and Drug Administration as a medical device for reuse.

(ii) The sharps container must be permanently marked for reuse.

(iii) The sharps container must be disinfected prior to reuse by any means

effective for the infectious substance the container previously contained.

(iv) The sharps container must have a capacity greater than 7.57 L (2 gallons) and not greater than 151.42 L (40 gallons) in volume.

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

§ 173.199 Diagnostic specimens and used health care products.

(a) *Diagnostic specimens.* Except as provided in this paragraph (a), diagnostic specimens are excepted from all 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 meeting 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). The outer packaging 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, conforming 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 leakproof.

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

(d) *Used health care products.* A used health care product being returned to the manufacturer or the manufacturer's designee is 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 primary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. For a used health care product capable of cutting or penetrating skin or packaging material, the primary container 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 conforming to 29 CFR 1910.1030(g)(1)(i).

(2) Each primary container must be placed inside a watertight secondary container designed and constructed to assure that it remains intact under conditions normally incident to transportation. The secondary container

must be marked with a BIOHAZARD marking conforming 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 know about the requirements of this section.

PART 177—CARRIAGE BY PUBLIC HIGHWAY

19. The authority citation for part 177 continues to read as follows:

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

20. In § 177.834, paragraphs (a) and (g) are 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 and containing 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 loaded to minimize the likelihood of damage thereto during transportation.

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21. In § 177.843, paragraph (d) is added to read as follows:

§ 177.843 Contamination of vehicles.

* * * * *

(d) Each transport vehicle used to transport Division 6.2 materials must be

disinfected prior to reuse if a Division 6.2 material is released from its packaging during transportation. Disinfection may be by any means effective for neutralizing the material released.

PART 178—SPECIFICATIONS FOR PACKAGINGS

22. The authority citation for part 178 continues to read as follows:

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

23. In § 178.503, paragraph (f) is added to read as follows:

§ 178.503 Marking of packagings.

(f) A manufacturer must mark every UN specification package 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 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.

24. In § 178.601, paragraphs (c)(1), (c)(2), and (e) are 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 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.

25. In § 178.609, the section heading, the text of 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) are 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, categorizes 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 that 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;

(iii) Flat on the longest side;

(iv) Flat on the shortest side; and

(e) The samples must be subjected to a water spray to simulate 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). For a successful 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 the steel rod will impact the primary receptacle(s). For a successful test, 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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Ellen G. Engleman,

Administrator, Research and Special Programs Administration.

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