

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****49 CFR Parts 171, 172, 173, and 175**

[Docket No. PHMSA-2004-16895 (HM-226A)]

RIN 2137-AD93

Hazardous Materials: Infectious Substances; Harmonization With the United Nations Recommendations

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is revising the transportation requirements for infectious substances, including regulated medical waste, to adopt new classification criteria, new exceptions, and packaging and hazard communication requirements consistent with revised international standards and to clarify existing requirements to promote compliance. These revisions will ensure an acceptable level of safety for the transportation of infectious substances and facilitate domestic and international transportation.

EFFECTIVE DATE: This final rule is effective October 1, 2006.

Voluntary Compliance Date:

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

On May 19, 2005, the Pipeline and Hazardous Materials Safety Administration (PHMSA), published a notice of proposed rulemaking (NPRM) to revise the requirements in the Hazardous Materials Regulations (HMR; 49 CFR parts 171-180) applicable to the transportation of infectious substances affecting humans and animals, including regulated medical waste (67 FR 53118). In the NPRM, PHMSA proposed to harmonize the HMR requirements applicable to the transportation of Division 6.2 materials with requirements in the 13th and 14th Editions of the UN Recommendations for the Transport of Dangerous Goods

(UN Recommendations), the 2005-2006 Edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the International Maritime Organization Dangerous Goods Code. Specifically, we proposed to:

- Revise the classification system for Division 6.2 materials from the current four-tiered risk group system to a two-tiered system—Category A and Category B.

- Replace the proper shipping name “Diagnostic specimens” with “Biological substance, Category B.”

- Adopt packaging requirements for Category A and Category B infectious substances consistent with those in the UN Recommendations and ICAO Technical Instructions.

- For Category B infectious substances, require the name, address, and telephone number of a person knowledgeable about the Category B infectious substance to be provided on a written document, such as an air waybill, accompanying the shipment or on the package.

- Permit a sample of an unknown infectious substance shipped for analysis or diagnosis to be transported as a Category B infectious substance, unless there is a strong suspicion that the unknown infectious substance meets the criteria for Category A, in which case the unknown material must be transported as a Category A infectious substance.

- Require sharps packagings to be securely closed and leakproof in all orientations.

- Require the development and implementation of transportation security plans for select agents and toxins affecting animals, as identified in 9 CFR part 121.

The comment period for the proposed rule closed on July 18, 2005. PHMSA received 13 comments, all of which support revising the requirements to harmonize them with current international standards. The following companies, organizations, and individuals submitted comments: Gary Gilliam (Gilliam; RSPA-2004-16889-2); Alcoa, Inc. (Alcoa; RSPA-2004-16889-3); Steven V. Schulte (Schulte; RSPA-2004-16889-4); The Daniels Corporation (Daniels; RSPA-2004-16889-6); Shoolah Escott (Escott; RSPA-2004-16889-7); National Solid Waste Management Association/Medical Waste Institute (NSWAM/MWI; RSPA-2004-16889-8); American Blood Centers (ABC; RSPA-2004-16889-9); Air Transport Association of America, Inc. (ATA; RSPA-2004-16889-10);

Stericycle, Inc. (Stericycle; RSPA-2004-16889-11); JBM Associates, Inc. (JBM; RSPA-2004-16889-12); American Clinical Laboratory Association (ACLA; RSPA-2004-16889-13); Air Line Pilots Association (ALPA; RSPA-2004-16889-14); and TEN-E Packaging Services, Inc. (TEN-E; RSPA-2004-16889-15 and -16).

II. Discussion of Comments*A. Classification of Division 6.2 Materials*

The HMR currently incorporate a risk-group-based classification system for infectious substances. The regulations require Division 6.2 materials to be assigned to risk groups based on the degree to which they cause injury through disease, with Risk Group 1 presenting the lowest risk and Risk Group 4 presenting the highest risk. Assignment of an infectious substance to a risk group is based on the known medical history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal. Division 6.2 materials assigned to Risk Group 1 are excepted from the HMR and the UN Recommendations.

The current requirements for assigning pathogens to risk groups are based on the risks posed in the laboratory environment, not in the transportation environment. Pathogens in transport do not pose the same level of risk that they do in the laboratory. Laboratory workers perform extensive manipulations of infectious substances that place the workers at higher risk of infection because of accidental exposures caused by splashes or spills. Moreover, certain laboratory processes—such as vortexing, mixing, or centrifuging—can generate aerosols or airborne particles that can place workers who perform such operations at increased risk. These conditions do not exist in transport.

The risk group classification system resulted in transportation problems, including shipper confusion in assigning risk groups, and shipment delays or refusal to transport associated with carriers' and transport workers' perceptions about the risks associated with the transportation of infectious substances. A delay in transportation or a refusal to transport a specimen may have life-threatening implications for a patient or a population. Moreover, transportation problems can delay research necessary to develop treatments or slow the spread of disease, and can interfere with the

implementation of appropriate measures to address new disease outbreaks. Because of these transportation problems, the UN Committee of Experts on the Transport of Dangerous Goods worked with scientists and public health professionals at the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), and other agencies to develop a classification scheme for infectious substances that would be more appropriate for the transportation environment.

In December 2002, the United Nations adopted a number of revisions for the 13th Revised Edition of the UN Recommendations related to the transportation of infectious substances, primarily involving how infectious substances are classed and packaged. In July 2004, the UN Committee of Experts on Dangerous Goods recommended further revisions to these standards; these revisions were adopted for the 14th Revised Edition of the UN Recommendations in December 2004. At the same time, the ICAO Dangerous Goods panel adopted many of the amendments for the 14th Revised Edition of the UN Recommendations in the 2005–2006 Edition of the ICAO Technical Instructions through an addendum to the ICAO Technical Instructions.

The amendments in the 13th and 14th Editions of the UN Recommendations are the result of long and thoughtful consultations among regulators, scientists, medical professionals, and the transport community. The result is a set of standards for the transportation of infectious substances that are easier to use and impose a high level of safety appropriate to the degree of risk and conditions of transport. PHMSA's May 9, 2005 NPRM proposed to harmonize HMR requirements for the transportation of infectious substances with the international standards.

Commenters generally support PHMSA's efforts to more closely align the requirements for transporting infectious substances with current international requirements by adopting a two-tiered classification system. The majority of commenters state they believe the requirements will ease the movement of these materials in transit and reduce confusion, thereby increasing safety. Therefore, in this final rule, we are adopting the classification system as proposed in the NPRM.

The requirements adopted in this final rule establish a two-tiered classification system for Division 6.2 materials—Category A and Category B. Category A infectious substances pose a higher degree of risk than Category B infectious substances. Category A

material is an infectious substance transported in a form capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Category A infectious substances are assigned to existing identification numbers UN 2814 (for substances causing disease in humans or in both humans and animals) or UN 2900 (for substances causing disease in animals only), and are to be packaged and described according to applicable HMR provisions for these materials. The following are examples of Category A infectious substances, as designated by scientists at WHO and the U.S. Department of Health and Human Services (HHS). Please note this list is not all inclusive and is provided only as guidance. Note also that many of the entries on the list include the modifier “(cultures only).” For these materials, only cultures of the listed infectious substances are considered Category A infectious substances. Other forms of these infectious substances may be transported as Category B infectious substances.

Category A infectious substances UN No. and proper shipping name	Micro-organism
UN 2814—Infectious substances affecting humans and animals	Bacillus anthracis (cultures only). Brucella abortus (cultures only). Brucella melitensis (cultures only). Brucella suis (cultures only). Burkholderia mallei—Pseudomonas mallei—Glanders (cultures only). Burkholderia pseudomallei—Pseudomonas pseudomallei (cultures only). Chlamydia psittaci—avian strains (cultures only). Clostridium botulinum (cultures only). Coccidioides immitis (cultures only). Coxiella burnetti (cultures only). Crimean-Congo hemorrhagic fever virus. Dengue virus (cultures only). Eastern equine encephalitis virus (cultures only). Escherichia coli, verotoxigenic (cultures only). Ebola virus. Flexal virus. Francisella tularensis (cultures only). Guanarito virus. Hantaan virus. Hantaviruses causing hemorrhagic fever with renal syndrome. Hendra virus. Herpes B virus (cultures only). Human immunodeficiency virus (cultures only). Highly pathogenic avian influenza virus (cultures only). Japanese Encephalitis virus (cultures only). Junin virus. Kyasanur forest disease virus. Lassa virus. Machupo virus. Marburg virus. Monkeypox virus. Mycobacterium tuberculosis (cultures only). Nipah virus.

Category A infectious substances UN No. and proper shipping name	Micro-organism
UN 2900—Infectious substances affecting animals only	Omsk hemorrhagic fever virus. Poliovirus (cultures only). Rabies and other lyssaviruses (cultures only). Rickettsia prowazekii (cultures only). Rickettsia rickettsia (cultures only). Rift Valley fever virus (cultures only). Russian spring-summer encephalitis virus (cultures only). Sabia virus. Shigella dysenteriae type I (cultures only). Tick-borne encephalitis virus (cultures only). Variola virus. Venezuelan equine encephalitis virus (cultures only). Vesicular stomatitis virus (cultures only). West Nile virus (cultures only). Yellow fever virus (cultures only). Yersinia pestis (cultures only). African swine fever virus (cultures only). Avian paramyxovirus Type 1—Velogenic Newcastle disease virus (cultures only). Classical swine fever virus (cultures only). Foot and mouth disease virus (cultures only). Lumpy skin disease virus (cultures only). Mycoplasma mycoides—Contagious bovine pleuropneumonia (cultures only). Peste des petits ruminants virus (cultures only). Rinderpest virus (cultures only). Sheep-pox virus (cultures only). Goatpox virus (cultures only). Swine vesicular disease virus (cultures only).

A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance does not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. Under the provisions of the 13th Edition of the UN Recommendations, adopted in December 2002, a Category B infectious substance is described as “Diagnostic Specimen” or “Clinical Specimen” and assigned to UN 3373.

Currently, the HMR define a “diagnostic specimen” to mean any human or animal material being transported for diagnostic or investigative purposes. In accordance with current § 173.199, diagnostic specimens are excepted from most HMR requirements except for minimal packaging and hazard communication. Historically, the HMR have permitted a proper shipping name, such as “Diagnostic specimen,” listed in the § 172.101 Table to be used to describe a non-hazardous material on a shipping paper and package marking provided the UN or NA identification number is not included. See §§ 172.202(e) and 172.303(b)(3). However, adoption of the proper shipping name “Diagnostic specimen” in both the international standards and the HMR resulted in some confusion on the part of both shippers and carriers who are accustomed to using these terms to refer

to human or animal samples that have a low probability of containing an infectious pathogen. In addition, using these terms to describe shipments of Category B infectious substances is not completely accurate—there are many shipments of Category B infectious substances that may not be diagnostic specimens as that term is usually defined.

The UN Sub-Committee of Experts on the Transport of Dangerous Goods discussed the proper shipping name issue during its July 2004 meeting and agreed to adopt a different proper shipping name for Category B infectious substances—“Biological substance, Category B.” The UN adopted this proper shipping name for the 14th Revised Edition of the UN Recommendations, which is effective January 1, 2007; ICAO adopted the new proper shipping name through an addendum to the 2005–2006 ICAO Technical Instructions. The addendum permits use of the new proper shipping name as an alternative to “Diagnostic Specimen” or “Clinical Specimen” until January 1, 2007, at which time the new name must be used. Consistent with the revised international standards, the May 9, 2005 NPRM proposed to adopt the proper shipping name “Biological substance, Category B” in the HMR. No commenters opposed this proposal, and it is adopted in this final rule. Thus, a Category B infectious substance must be

described as “Biological substance, Category B” and assigned to UN 3373.

B. Packaging Requirements for Category B Infectious Substances

Currently, the HMR require Risk Group 2 and 3 infectious substances (most of which will be classed as Category B infectious substances under this final rule) to be transported in triple packagings certified to comply with the performance standards in § 178.609, including a drop test from a height of 9 m (30 ft), a water spray test, and a puncture test. In the NPRM, we proposed to permit Category B infectious substances to be transported in non-specification triple packagings capable of passing a drop test only at a height of 1.2 meters (3.9 feet). Commenters support this proposal. We are adopting this requirement in this final rule.

The NPRM proposed to require these packagings to be capable of passing the drop test set forth in § 178.603, which prescribes tests for all non-bulk packaging designs. As suggested by one commenter (TEN–E), in this final rule, we are replacing the reference to § 178.603 with § 178.609. The drop test established in § 178.609 applies specifically to infectious substance packagings; this testing configuration more appropriately addresses the integrity issues for infectious substance packages.

The NPRM proposed to require the outer packaging of the triple pack authorized for the transportation of Category B infectious substances to be rigid; the proposal is consistent with requirements adopted for air shipments of Category B infectious substances in the ICAO Technical Instructions. One commenter (ACLA) suggests this requirement is unnecessary because a packaging capable of passing a 1.2 meter drop test has sufficiently demonstrated it can withstand normal transportation conditions. The commenter states this requirement would impose unnecessary costs on clinical laboratories with no safety benefit. We disagree. As indicated above, Category B packagings must be capable of passing a drop test, but need not be capable of passing a puncture or other performance test. A requirement for a rigid outer packaging will help to ensure that the entire package can withstand punctures and other conditions that may be encountered during transportation and particularly at package sorting facilities. In addition, a rigid outer packaging will help to ensure that package markings are intact and legible in the event the package is damaged during transportation. We therefore find the safety benefits of a requirement for a rigid outer packaging outweigh the minimal additional cost of such packaging. However, we do agree a rigid packaging conforming to HMR requirements may be placed inside an envelope or other non-rigid overpack conforming with § 173.25 of the HMR.

The commenter (ACLA) also asks us to provide guidance concerning what constitutes a rigid outer packaging. An outer packaging is defined under § 171.8 as the outermost enclosure of a composite or combination packaging together with any absorbent materials, cushioning, and any other components necessary to contain and protect inner receptacles or inner packagings. A rigid packaging is sufficiently stiff and unyielding so as to retain its original shape and dimensions at all times and under all conditions of transportation.

Current HMR requirements require infectious substances packed with materials intended to stabilize or prevent degradation of the sample to be transported in accordance with provisions applicable to the hazard class of the stabilizing material used. In the NPRM, we proposed to relax this requirement to except Packing Group II or III materials used to stabilize or prevent degradation of infectious materials up to a limit of 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging from HMR requirements. A commenter (ACLA) suggests we permit each inner packaging to contain up to

250 mL (25% of the total permitted volume of liquid material per primary receptacle) of Packing Group II or III material. We disagree. For shipments by air, the maximum quantity contained in each inner receptacle of the package may not exceed 1 L; the maximum quantity contained in each outer package may not exceed 4 L. Thus, the revision proposed by ACLA would permit as much as 1 L of a stabilizing material or preservative to be transported in a single package with no additional packaging or hazard communication requirements. Particularly for shipments transported by aircraft, we believe quantities of Packing Group II or III materials in excess of 30 mL pose a sufficient hazard as to require at least minimal regulation. The limit of 30 mL per inner receptacle is consistent with the small quantity exception in § 173.4, which excepts small quantities (up to 30 mL or 30 g per inner receptacle) of certain hazard materials from all HMR requirements provided minimal packaging requirements are met. Moreover, the triple packaging design for infectious substances is similar to the minimal packaging authorized for small quantities of hazardous materials under § 173.4. Thus, we are adopting the limitation on the quantity of preservative permitted in each inner packaging as proposed in the NPRM. If a shipper elects to use a larger quantity of preservative, the shipment must conform to HMR requirements applicable to the specific material and quantity being shipped.

Two commenters (Escott, JBM) asked us to clarify that the requirement for a pressure differential test for packagings used to transport Category B infectious substances applies only to transportation by aircraft. As discussed in the NPRM, this provision in existing § 173.199(b)(4) is not changed in this final rule. Either the primary or secondary receptacle for a liquid Category B infectious substance must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of 95 kPa (0.95 bar, 14 psi) when offered or intended for transport by aircraft.

C. Emergency Contact Information for Category B Infectious Substances

Currently, the HMR require packages of Risk Group 2 and 3 infectious substances (most of which will be classed as Category B infectious substances under this final rule) to be accompanied by shipping papers that include a telephone number that is monitored at all times the hazardous material is in transportation; the

telephone number must be the number of a person who is knowledgeable about the hazardous material being shipped and has comprehensive emergency response and incident mitigation information for that material (see § 172.604). Because Category B infectious substances are excepted from shipping paper requirements, in the May 9, 2005 NPRM, we proposed to require the proper shipping name; UN number; and name, address, and telephone number of a person knowledgeable about the material to be provided on a written document, such as an air waybill, accompanying a Category B infectious substance shipment or on the package itself. Two commenters object to the requirement for a contact telephone number. One commenter (Escott) suggests the expense of monitoring the number while the shipment is in transit would impose a significant cost burden on clinical laboratories, medical facilities, and other infectious substance shippers. A second commenter (JBM) suggests the address on the packaging should be sufficient for contacting the responsible party in the event of an incident.

This provision to add the emergency contact name and telephone number for Category B infectious substances is intended to harmonize hazard communication for these materials with requirements in the 2005–2006 ICAO Technical Instructions. The number need not be monitored at all times the hazardous material is in transportation, as would be required under § 172.604 of the HMR. However, we do intend it to be monitored during a company's administrative office hours. Thus, we expect the burden of complying with this requirement will be minimal. Consistent with revisions adopted by ICAO in November 2005, in this final rule, we are not requiring an address as part of the contact information. Emergency contact information shown on a shipping document or on the package must include the name and telephone number of a person knowledgeable about the shipment.

We disagree that the number should not be required. Having access to a telephone number will enable transport workers and emergency responders to contact a person knowledgeable about the shipment within a reasonable period of time and, thus, will facilitate the retrieval of information concerning the material and its potential hazards.

D. Exceptions for Certain Shipments

The HMR currently except certain shipments of infectious substances from all regulatory requirements when the shipments are transported by a private

or contract carrier in a motor vehicle used exclusively to transport these materials. In the NPRM, we propose to expand this exception to Category B infectious substances transported for research, diagnosis, investigational activities, or disease treatment or prevention. One commenter (Escott) recommends the HMR include minimal packaging requirements for such shipments, such as non-specification triple packagings with absorbent material, and minimal marking and labeling requirements. Escott states, "When I worked in a hospital, I received specimens that were transported by a courier and were leaking * * *" We do not agree Category B shipments transported by private or contract carriers should be regulated under the HMR. We do not have reports of safety problems involving courier shipments of infectious materials under the exception currently provided in the HMR. Courier shipments typically are packaged in primary receptacles, sealed in leak-proof plastic bags, and placed in a leak proof outer container that includes cushioning material. 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 handling potentially infectious materials. Requiring additional packaging and hazard communication requirements would add to the cost of shipping such materials without improving safety. Therefore, we are adopting the exception as proposed in the NPRM.

In the NPRM, we indicated the HMR do not apply to a human or animal sample transported for routine testing when the testing is not related to the diagnosis of an infectious disease and when there is no reason to suspect the sample is infectious. Routine screening tests include: (1) Blood or urine tests a doctor may order as part of a routine medical examination to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); (2) blood or urine tests to monitor liver or kidney functions in individuals who are not known to have an infectious disease and who are following a particular drug therapy regime; (3) blood or urine tests conducted for insurance or employment purposes and/or intended to determine the presence of alcohol or drugs; (4) DNA tests; and (5) pregnancy tests. Routine tests for diagnoses for other than the presence of pathogens include biopsies to detect cancer and antibody titre testing. This exception proposed in the NPRM is consistent with exceptions

adopted in the UN Recommendations for substances unlikely to cause disease in humans or animals, and substances for which there is a low probability an infectious pathogen is present.

Three of the four commenters addressing this issue (ACLA, Alcoa, ABC), support the exception from the HMR for transporting specimens from apparently healthy individuals and animals for routine diagnostic testing for other than an infectious disease. These commenters state many years of experience shows the probability of such samples being infectious is low, and, therefore, their transportation is unlikely to compromise safety. These commenters also state permitting the transportation of samples from apparently healthy individuals for routine testing will facilitate the processing of such samples and initiation of appropriate patient treatment. One commenter (JBM) opposes the exception. The commenter suggests samples from apparently healthy individuals may contain pathogens and recommends minimal packaging standards to guard against the release of the sample during transportation.

We agree with the commenters who suggest that samples from apparently healthy individuals and animals being transported for routine testing unrelated to the diagnosis of an infectious disease are not likely to be infectious and, thus, pose a minimal safety risk. Patient specimens excepted from regulation under the HMR are those from persons believed by professional judgment to have a minimal likelihood of harboring an infectious agent. These specimens typically are blood, serum, urine, stool, biopsies, hair, finger or toe nails, semen, or other similar samples from a body. According to health care specialists and scientists at WHO and the U.S. Department of Health and Human Services, the risk of infection during transportation from samples taken from apparently healthy patients and animals and transported for routine testing is extremely small. Therefore, we are adopting the exception from HMR requirements for such samples as proposed in the NPRM.

Shippers and carriers should be aware ICAO has adopted minimal standards applicable to the transportation of human or animal specimens for which there is minimal likelihood that pathogens are present. Such specimens are not subject to ICAO requirements when they are transported in a packaging designed to prevent any leakage and marked with the words "Exempt human specimen" or "Exempt animal specimen," as applicable. This is

a mandatory ICAO requirement; however, we are not adopting it in this final rule. Such samples are not transported in a quantity or form that poses an unreasonable risk to health and safety. Thus, for purposes of the HMR, such specimens are not considered hazardous materials and are not subject to any requirements. Note that use of the "Exempt human specimen" or "Exempt animal specimen" marks by a shipper indicates that the relevant packages do not contain a hazardous material. Therefore, packages bearing these marks may be accepted by air carriers making a business decision to not accept hazardous materials. Conversely, packages bearing the Proper Shipping Names "Infectious Substance, affecting humans" or "Infectious Substance, affecting animals" or "Biological Substance, Category B" must be rejected by air carriers making a business decision to not accept hazardous materials.

E. Notification to Pilot-in-Command

Generally, a notification to the pilot-in-command (NOPIC) is required for shipments of hazardous materials subject to the HMR or ICAO Technical Instructions. The NOPIC includes the proper shipping name, hazard class, and identification number of the hazardous material; the total number of packages; the net quantity or gross weight for each package; the location of the packages on the aircraft; any additional information required by the regulations; and confirmation that no damaged or leaking packages have been loaded on the aircraft (see § 175.33 of the HMR and Chapter 4, paragraph 4.1.1, and Chapter 7, paragraph 7.4.1 of the ICAO Technical Instructions). The NOPIC provides the pilot-in-command with information to make critical decisions and take necessary safety precautions in the event of an emergency on board the aircraft.

In the preamble to the NPRM, we indicated, consistent with the ICAO Technical Instructions, we were not proposing to require a NOPIC for air shipments of Category B infectious substances. We noted that ICAO narrowly decided against such a requirement for the 2005–2006 Edition of the ICAO Technical Instruction. ICAO members opposed to the requirement cited the low risk in transportation associated with Category B infectious substances, new ICAO requirements for hazard communication for Category B shipments, and the possibility that increased regulation would result in fewer carriers electing to transport Category B shipments. Members supporting the NOPIC

requirement cited the benefit of information being available to the pilot and emergency responders in the event of an emergency or an accident. We invited commenters to address this issue, and whether or not the HMR should require a NOPIC for shipments of Category B infectious substances.

Of the three commenters who address this issue, two (ATA, ACLA) support the ICAO decision to not require a NOPIC for Category B infectious substances. These commenters note Category B infectious substances pose a reduced risk in transportation because they do not cause permanent disability or life-threatening or fatal disease to humans or animals. These commenters agree the hazard communication requirements in the ICAO Technical Instruction provide sufficient information for package handlers and emergency responders to make necessary safety decisions in the event of an emergency. The commenters also state the NOPIC provision would increase administrative and training costs and could result in the refusal by some carriers to transport these materials. The ultimate impact of a NOPIC provision in the HMR, according to these commenters, could be to impede or delay transportation of Category B infectious substances.

One commenter (ALPA) supports a requirement for a NOPIC for shipments of Category B infectious substances. This commenter suggests a NOPIC is necessary to enable transport workers to make informed judgments concerning the segregation and loading of packages and enhances the ability of the pilot in command to make potentially life-saving decisions concerning the occupants of his or her aircraft and to advise emergency personnel.

As indicated above, Category B infectious materials pose a reduced risk in transportation because they do not cause life-threatening or fatal disease in otherwise healthy humans or animals. The hazard communication requirements adopted in this final rule are adequate to assure transport workers exercise care in handling packages of Category B materials and protect themselves if they discover a damaged or leaking package. We agree with commenters who suggest the impact of requiring a NOPIC for shipments of Category B infectious materials would be to impede or delay transportation of these shipments; such delays could adversely affect patient treatment and public health. Therefore, we are not adopting a requirement for a NOPIC for shipments of Category B infectious substances in this final rule.

F. Regulated Medical Waste

The HMR currently define regulated medical waste (RMW) to mean a waste or reusable material known to contain or suspected to contain 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. In the NPRM, we proposed to revise this definition to mean a waste or reusable material known to contain or suspected to contain a Category B infectious substance. In accordance with the definition proposed in the NPRM, RMW containing a Category A infectious substance must be classed as Division 6.2, described as an infectious substance affecting humans or affecting animals only, as appropriate, assigned to UN 2814 or UN 2900, and transported in accordance with all applicable requirements. Medical waste containing a Category A infectious substance may not be transported under the shipping name "Regulated medical waste, n.o.s.," UN 3291. Medical waste containing a Category A infectious substance must be described as "Infectious substances, affecting humans" or "Infectious substances, affecting animals," assigned to UN 2814 or UN 2900, and packaged in a UN specification packaging conforming to the requirements of § 173.196 of the HMR. Infectious medical waste containing a Category A infectious substance is not excepted from regulation under 173.134(c) of the HMR when transported by private or contract carriers.

One commenter (Stericycle) expresses concern about the NPRM's treatment of RMW containing a Category A infectious substance, suggesting the proposals could be confusing for facilities generating RMW and the carriers transporting them. The commenter asks us to consider permitting RMW containing a Category A infectious substance to be transported as "Regulated medical waste, n.o.s.," UN 3291, noting that about one-half of the materials listed in the preamble to the NPRM as Category A infectious materials are currently assigned to Risk Group 2 or 3 materials permitted to be transported as RMW under UN 3291.

The requirements adopted in this final rule for the transportation of RMW containing a Category A infectious substance are the same as the current HMR requirements for the transportation of RMW containing a Risk Group 4 infectious substance. A Category A infectious substance is one

transported in a form capable of causing permanent disability or life-threatening or fatal disease to an otherwise healthy human or animal when exposure to it occurs. Certain Category B infectious substances in culture form pose a significant risk in transportation and were added to the Category A list under the regulations of the UN Recommendations, ICAO Technical Instructions, and the IMDG Code. We have adopted this provision as proposed in the NPRM to harmonize with these requirements.

As Stericycle notes, a number of the infectious agents on the list of Category A infectious substances are currently considered Risk Group 2 or 3 materials. However, they are included on the Category A list only as cultures—that is, when the pathogen is intentionally propagated. Most cultured infectious substances are not transported for disposal, but are destroyed or rendered non-infectious onsite. In all other forms, these materials are considered Category B infectious substances and may be transported as "Regulated medical waste, n.o.s.," UN 3291. Requiring infectious medical waste containing a Category A infectious substance to be transported as an infectious substance, UN 2814 or 2900, appropriately addresses the risks posed by these materials. Therefore, we are adopting the requirements applicable to the transportation of RMW as proposed in the NPRM. RMW containing a Category A infectious substance should be handled and managed at medical facilities in the same manner as RMW containing a Risk Group 4 infectious substance is currently handled.

G. Sharps Containers

As currently required under the HMR, sharps containers generally must comply with § 173.197, which requires sharps to be in a UN specification packaging that is puncture resistant for sharps and sharps with residual fluid, as demonstrated by conformance with the design and test requirements in subpart M of part 178 at the Packing Group II performance level. The performance tests must be conducted with the packaging assembled as if for transportation, including with the closure secured as it would be for transportation. A sharps container that conforms to these requirements need not be placed in an outer packaging for transport. Under § 178.2(c), the packaging manufacturer must provide each person to whom the packaging is sold or transferred with a notification in writing specifying the types and dimensions of the closures, including gaskets and any other components

needed to assure the packaging is capable of passing the required tests. This notification must also include any procedures to be followed, including closures for inner packaging and receptacles, to enable a shipper to effectively assemble and close the package to prevent leakage during transportation.

A sharps container placed inside a bulk packaging, such as a UN specification Large Packaging or a non-specification bulk outer packaging or wheeled cart, must be puncture resistant. A sharps container that is 20 gallons or less in volume need not be a UN specification packaging if it is to be placed in a bulk outer packaging. A sharps container that is larger than 20 gallons in volume that is placed inside a bulk packaging must be capable of passing the performance tests in subpart M of part 178 at the Packing Group II performance level. A sharps container that will be placed in a bulk outer packaging for transportation may be reused only if it is specifically cleared or approved by FDA as a medical device for reuse and must have a capacity of between 2 and 40 gallons.

The HMR include an exception from certain requirements for regulated medical waste (RMW), including sharps, transported by a private or contract carriers (see § 173.134(c)). Under this exception, RMW, including sharps, may be transported in a rigid, non-bulk packaging that conforms to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in OSHA standards at 29 CFR 1910.1030. The packaging requirements in §§ 173.24 and 173.24a address general packaging issues such as packaging integrity, filling limits, and closures. Specifically with regard to leakproofness, § 173.24(f) requires closures to be leakproof and secured against loosening. The OSHA standards at 29 CFR 1910.1030 require sharps containers to be puncture resistant and leakproof (see 1910.1030(d)(4)(iii)(A)(1)).

The NPRM proposed to clarify that sharps containers must be securely closed to prevent leaks or punctures based on our enforcement experience indicating insecure closures permit sharps to protrude from sharps containers during transportation. In the last two years, we have initiated five civil enforcement cases related to inadequate closures on sharps containers; there have been a number of other instances where an inspector identified problems with the closures, but did not initiate a civil enforcement action. One commenter (Gillian) states "single use sharps container lids * * *

will come off inside a transport container * * *. Some 40% of these containers have the lid dislodged in transport spilling their contents into the red bag." The commenters who address this issue (Gillian, NSWMA/MWI, Stericycle) are concerned the proposed requirement is not sufficiently precise and does not include sufficient guidance on the procedures to be followed to ensure compliance by container manufacturers or shippers. To address commenters' concerns that the proposal concerning closures was not sufficiently precise, in this final rule, we are modifying the provisions to specify a sharps packaging must be securely closed to prevent punctures or leakage during transportation in accordance with the instructions provided by the packaging manufacturer.

In the NPRM, we discussed Food and Drug Administration (FDA) requirements for sharps containers regulated as medical devices subject to pre-market review by FDA and asked commenters to address whether the HMR should permit FDA-cleared or -approved sharps containers to be used for the transportation of sharps and, if so, under what circumstances. The two commenters who addressed this issue had mixed views. One commenter (NSWMA) opposes the use of FDA-cleared sharps containers for transportation unless the container conforms in all respects to the HMR requirements in §§ 173.197 and 173.134. The commenter notes FDA's review process is intended to address whether the device is reasonable safe and effective for its intended use in hospital, laboratory, or healthcare facility settings, not in transportation. A second commenter (Stericycle), however, asserts the FDA requirements address the integrity of the material used to make sharps containers and assure containers meet puncture-resistance criteria and are leak-proof on the sides and bottom. This commenter recommends the HMR require all sharps to be transported in FDA-cleared containers.

As we stated in the preamble to the NPRM, sharps containers cleared or approved by FDA may not meet current HMR requirements in §§ 173.134 and 173.197. For example, the FDA review process is designed to determine, among other things, whether sharps containers are leak resistant on the sides and bottom and whether closures are leak resistant. This is a lesser standard than the leak-proofness standard established in the HMR. For this reason, we disagree with the commenter who recommends the HMR require all sharps to be transported in FDA-cleared containers.

FDA-cleared sharps containers may be used to transport sharps provided the container conforms to applicable HMR requirements or the sharps container is placed inside a leak-proof outer packaging.

Two commenters express concern about the current requirement in the HMR for sharps containers to be leak-proof. One commenter (Stericycle) notes certain sharps containers are designed specifically to allow for venting to assure steam penetration during autoclaving and suggests the leak-proofness standard negatively impacts the effectiveness of autoclaving. This commenter suggests there are safe and effective alternatives to a leak-proofness standard for transportation, such as requiring containers to be positioned in an upright position in a transport vehicle or requiring absorbent material in sharps containers. Another commenter (Daniels) is concerned the HMR do not include a leak-proofness test standard. This commenter asserts sharps containers should be required to be leak-proof without secondary containment and proposes a leak-proofness test for incorporation into the HMR.

We did not propose in the NPRM to modify the current requirements for sharps containers to be leakproof. Thus, the comments concerning these requirements are beyond the scope of this rulemaking. However, we may consider revising the requirements for sharps containers in a future rulemaking.

H. Miscellaneous Comments

The HMR currently require air carriers to inspect all hazardous materials packages prior to transportation to ensure that the package conforms to HMR requirements and has no holes, leakage, or other indication that its integrity has been compromised (see § 175.30 (b)). Except for radioactive materials packages, there are no current requirements for inspecting packages for signs of leakage when they are unloaded from an aircraft. In the NPRM, we proposed to require for air transportation each package and overpack containing a Division 6.2 material to be inspected for signs of leakage. If evidence of leakage is discovered, the cargo compartment in which the package or overpack was transported must be disinfected. This proposal is consistent with the inspection requirements for air shipments in the ICAO Technical Instructions. One commenter (ALPA) suggests this requirement should also apply to packages of Division 6.2 materials transported on pallets or in

unit load devices. We agree, and are adopting this change in this final rule.

One commenter (JBM) asks us to clarify the difference between the exception for medical equipment in § 173.134(b)(12) and the requirements for the transportation of used health care products in § 173.199. In accordance with § 173.134(b)(12), medical equipment, including equipment intended for use, cleaning, or refurbishment is excepted from the HMR when it is transported in accordance with standards established by the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1030. The regulations in § 173.199 are intended for the transportation of used health care products that do not conform to the OSHA standards.

A commenter (Schulte) suggests we move the requirements for the transportation of used health care products from § 173.199 and relocate them to § 173.134. The commenter states placing the requirements for used health care products in the same section as requirements for the transportation of Category B infectious substances suggests the risk from the transportation of used health care products is the same as for Category B infectious substances. We agree; in this final rule, we are relocating the requirements for used health care products currently in § 173.199(d) to § 173.134(b)(12)(ii).

III. Section-by-Section Review

This section-by-section review summarizes the changes adopted in this final rule.

Part 171

Section 171.8. In § 171.8, we are removing the definition for Risk Group.

Part 172

Section 172.101. In the Hazardous Materials Table, we are making several revisions. Most importantly, we are removing the current entry for “Diagnostic Specimens” for consistency with the 14th Revised Edition of the UN Recommendations. We are adding an entry for “Biological substance, Category B.” This entry will apply to shipments of Category B infectious substances, which must be classed as Division 6.2, described as a “Biological substances, Category B,” and assigned to UN 3373.

In addition, we are revising the entries for “Infectious substances, affecting animals” and “Infectious substances, affecting humans” to delete Special Provision A81 (see discussion below).

Section 172.102. We are removing Special Provision A81, which permits

the quantity limits currently specified in the HMT for air shipments to be exceeded for shipments of body fluids packaged in accordance with § 173.196. This special provision is no longer necessary because paragraphs (b)(5) and (c)(6) of § 173.199 include quantity limits for air transportation applicable to shipments of Category B infectious substances.

Section 172.200. Consistent with requirements in the ICAO Technical Instructions, in § 172.200(b)(4) we are clarifying the shipping paper requirements do not apply to Category B infectious substances prepared in accordance with § 173.199 of the HMR. This is consistent with the requirements adopted for the UN Recommendations under Packing Instruction 650 and Special Provision 319, which except Category B infectious substances from shipping paper requirements.

Section 172.203. Under this final rule, unknown samples of infectious substances shipped for analysis and diagnosis may be transported in accordance with requirements for Category B infectious substances, because historically, materials meeting this definition have been transported in a similar manner with no adverse safety impact or increased risk to transport workers or the general public. For situations where the identity of the agent or pathogen is not known, but sufficient information is available to strongly suspect a Category A infectious substance, this final rule requires an indication on shipping papers that the sample contains a Category A infectious material. Suspected Category A infectious substances must be shipped in accordance with all applicable hazard communication and packaging requirements for Category A infectious substances. The determination as to whether to ship an unknown sample as a Category A or Category B infectious substance should be made by appropriate medical or public health officials based on known medical conditions and history of the source patient or animal, endemic local conditions, and symptoms of the source patient or animal. Thus, in paragraph (k) of § 172.203, we are authorizing a shipping paper accompanying a shipment of a suspected Category A infectious substance to include the words “suspected Category A infectious substance” in parentheses as an alternative to a technical name to describe the pathogen(s) it contains when the infectious substance is not known. Thus, the shipping description for a suspected Category A infectious substance affecting humans would read, “Infectious substances, affecting

humans (suspected Category A infectious substance), 6.2, UN 2814”. For known Category A pathogens, the technical name of the pathogen must be indicated.

Section 172.301. Consistent with the UN Recommendations, paragraph (b) of § 172.301 states technical names need not be marked on the outer packaging of Division 6.2 materials.

Section 172.800. We are requiring persons who offer for transportation or transport select agents and toxins regulated by USDA under 9 CFR part 121 to develop and implement security plans in accordance with requirements in Subpart I of part 172 of the HMR.

Part 173

Section 173.6. The current exception for materials of trade (MOTS) prohibits Risk Group 4 infectious substances from being transported as MOTS. We are modifying § 173.6(a)(4) to prohibit Category A infectious substances and suspected Category A infectious substances, rather than Risk Group 4 infectious substances, from being transported as materials of trade (MOTS). This amendment is consistent with the definition and classification criteria for infectious substances adopted for the UN Recommendations. In addition, we are modifying the packaging requirements for MOTS shipments of Division 6.2 materials. For consistency with international standards, we are limiting the amount of material each packaging may contain rather than the capacities of the packagings used. Finally, we are adding a requirement for sharps containers to be securely closed to prevent leaks or punctures. As indicated above, we are concerned the closures currently being used for sharps containers may not be adequate to assure no contents will be released during transportation.

Section 173.24a. We are modifying paragraph (c)(2) in § 173.24a to prohibit a package containing inner packagings of Division 6.2 materials from containing any other hazardous materials except for dry ice, liquid nitrogen, or small amounts of other hazardous material in Packing Groups II or III used to preserve or stabilize the infectious substance. Hazardous materials most commonly used to preserve or stabilize an infectious substance include methanol, isopropyl alcohol, boric acid, formaldehyde, formalin, and sodium borate. This provision is consistent with a provision adopted for the 2005–2006 edition of the ICAO Technical Instructions and by the UN Transport of Dangerous Goods Subcommittee for the 14th Revised Edition of the UN Recommendations.

The packaging requirements for Division 6.2 materials, which include triple packaging and absorbent material, are comparable to the packaging permitted for transporting hazardous materials in accordance with the small quantity exceptions in § 173.4 and should minimize the risk of a release in transportation. Therefore, when a hazardous preservative, such as a Class 3 or Class 8 material in Packing Groups II or III, is included in the inner packaging with the material, the preservative is not be subject to HMR requirements provided the amount in the inner packaging does not exceed 30 mL for a liquid or 30 g for a solid. The maximum quantity in an outer package, including a hazardous material used to preserve or stabilize a sample, may not exceed 4 L or 4 kg. Note this exception applies only to materials in Packing Groups II or III; PG I materials are not authorized. Note also, for amounts in excess of 30 mL or 30 g per inner packaging, hazardous preservative materials are regulated under the HMR and must be transported in accordance with requirements applicable to their specific classification and characteristics.

Section 173.134. We are making a number of revisions to § 173.134 for consistency with definitions and provisions adopted for the UN Recommendations, as follows:

(1) We are modifying the definition for a Division 6.2 material. The definition adopted in this final rule replaces the Risk Group ranking system with the two-tiered Category A and Category B system adopted by the UN Recommendations. The definition includes a requirement for a Division 6.2 material to be assigned an appropriate identification number: UN 2814 for Category A infectious substances affecting humans or both humans and animals; UN 2900 for Category A infectious substances affecting animals only; UN3373 for Category B infectious substances; and UN 3291 for Regulated medical waste.

(2) We are modifying the definition for "biological product" to replace the Risk Group ranking references with references to Category A and Category B infectious substances.

(3) We are adopting a definition for "cultures" consistent with the definition for "cultures" adopted in the UN for the 14th Revised Edition of the UN Recommendations. Cultures are the result of a process by which pathogens are intentionally propagated by use of ideal conditions, including temperature, environment, and nutrient-based propagation media. The definition adopted in this final rule refers to

cultures prepared for the intentional generation of pathogens and does not include patient specimens intended for diagnostic or clinical purposes.

(4) We are adopting a new definition for "patient specimen." As defined in this final rule, "patient specimen" means human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Examples include excreta, secreta, blood and its components, tissue and tissue swabs, and body parts.

(5) We are modifying the definition for "regulated medical waste" to incorporate Category A and Category B infectious substances. RMW containing a Category A infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. RMW containing Category B infectious substances is assigned to UN 3291.

(6) We are modifying the listed exceptions in paragraph (b) of § 173.134 for consistency with the UN Recommendations. Most of the exceptions are unchanged. However, we are adding an exception for a material with a low probability of containing an infectious substance or where the concentration of the infectious substance is at a level naturally occurring in the environment that will not cause disease when exposure occurs. Examples include foodstuffs and certain environmental samples. The new provision referring to environmental samples would replace the exception for these materials in current § 173.134(b)(13). In addition, we are adding an exception for dried blood spots and for specimens used to detect fecal occult blood. These are specimens collected from healthy patients for routine testing and screening (e.g., DNA analysis, forensic studies, immunologic studies, cancer screening, and nutritional evaluations of infants, children, and adults). The specimen is placed on paper, allowed to saturate the paper, and then dried completely. The specimens pose an extremely minimal risk of infection, and may be rendered unusable if placed in packaging that retains moisture or heat to the sample. More than 100 million specimens have been safely transported by routine mail over the last 30 years. Health professionals recommend these materials should be transported in a double-envelope system forming a double-layer protective barrier (i.e., inner and outer-sealed high quality, air-permeable paper envelope) or an attached heavy paper fold-over flap

container placed into a secondary high-quality paper envelope.

In addition, in this final rule, we are excepting from regulation under the HMR a human or animal sample transported for routine testing not related to diagnosis of an infectious disease and for which there is no reason to suspect the sample is infectious. Routine screening tests include: (1) Blood or urine tests a doctor may order as part of a routine medical examination to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); (2) blood or urine tests to monitor liver or kidney functions for the millions of people who are not known to have an infectious disease and who are following a particular drug therapy regime; (3) blood or urine tests conducted for insurance or employment purposes and/or intended to determine the presence of alcohol or drugs; (4) DNA tests; and (5) pregnancy tests. Tests for diagnoses other than for the presence of pathogens include biopsies to detect cancer and antibody titre testing. This exception is consistent with exceptions adopted in the UN Recommendations for substances unlikely to cause disease in humans or animals and substances for which there is a low probability infectious substances are present.

(7) We are revising the exceptions in paragraph (c)(1) applicable to the transportation of regulated medical waste. We are adding a requirement for sharps containers shipped in accordance with this exception to be securely closed to prevent leaks or punctures. In addition, we are modifying paragraph (c)(2) to revise the current reference to Risk Group 2 or 3 infectious substances to Category B infectious substances.

(8) We are relocating requirements for transporting used health care products from § 173.199(d) to § 173.134(b)(12)(ii).

Section 173.196. We are modifying the Division 6.2 material packaging requirements in § 173.196 for consistency with the UN Recommendations. Generally, the revisions are editorial and do not change current packaging requirements. We are adding a requirement for outer packaging to be rigid. Note the packaging requirements in § 173.196 apply to shipments of Category A infectious substances only. The language describing the minimum size of the outer packaging is revised to clarify no external dimension of the packaging, i.e., no measurement on any outer surface of the packaging, shall be less than 100 mm (3.9 inches). Category B infectious substances are to be

transported in accordance with the provisions in § 173.199.

Section 173.197. We are modifying the RMW packaging requirements in § 173.197 to incorporate Category A and Category B infectious substances. The revisions do not substantively change the current packaging requirements for non-bulk or bulk shipments of RMW.

We are revising § 173.197(b) for clarification by correcting in the first sentence, “except as otherwise provided in § 173.134 of this subpart” to read “except as authorized by § 173.134(c).” In addition, in current paragraph (b) non-bulk RMW packaging is currently described as a DOT specification packaging meeting the requirements of Part 178 at the PG II performance level. We are revising the phrase “DOT specification” to read “UN standard” because non-bulk PG II refers to packagings in Part 178, Subpart L, conforming to a UN standard.

In § 173.197(d)(2)(iii), the reference to the drop test requirement prescribed in § 178.603 for non-bulk packagings is not correct. It should read “Each Cart must be capable of meeting the requirements of § 178.810 (drop test) at the Packing Group II performance level.” This section contains the drop test requirements for an intermediate bulk packaging.

In § 173.197(e)(3), in the introductory paragraph, we are revising the wording “the performance tests in § 178.601” to read “the performance tests in part 178, subpart M”. There are no performance tests in § 178.601. This revision makes § 173.197(e)(3) consistent with § 173.197(b). Finally, we are adding a requirement for sharps containers to be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. We are concerned the closures currently being used for sharps containers may not be adequate to ensure no contents will be released during transportation.

Section 173.199. We are modifying this section for consistency with the UN Recommendations and ICAO Technical Instructions. Under this final rule, the provisions of § 173.199 will apply to shipments of Category B infectious substances. The packaging requirements are substantially the same as the current requirements for shipping diagnostic specimens, except we are requiring the outer packaging to be rigid. The completed packaging must be capable of passing the drop tests in §§ 178.609(d) and (h) at a height of 1.2 meters (3.9 feet). We are adopting pass/fail criteria for the drop test—there must be no leakage from the primary receptacle, and the primary receptacle must remain

protected by absorbent material, when required, in the secondary packaging. In addition, we are requiring the use of absorbent materials for solids that may become liquid during transportation.

Consistent with amendments adopted for the UN Recommendations, we are removing the current capacity limitations for shipment of Category B infectious substances, except for Category B infectious substances transported by air. For air shipments of these materials, we are modifying the current limitations on capacity consistent with the amendments adopted in the 2005–2006 ICAO Technical Instructions. For liquids, we are increasing the amount of material permitted in each inner packaging from 500 mL (16.9 ounces) to 1 L (34 ounces); the limitation on the total amount of material permitted in the outer packaging remains 4 L (1 gallon). For solids, we are deleting the limitation on the amount of material permitted in each inner packaging; again, the limitation on the total amount of material permitted in the outer packaging remains 4 kg (8.8 pounds). We are also requiring at least one surface of the outer packaging to have a minimum dimension of 100 mm by 100 mm (3.9 inches).

Consistent with provisions proposed to be adopted for the 14th Edition of the UN Recommendations, we are requiring a package containing a Category B infectious substance and prepared in accordance with § 173.199 to be marked with the identification number “UN 3373” in a square-on-point configuration and with the proper shipping name “Biological substances, Category B.” Each side of the square-on-point mark must be at least 50 mm in length, and the proper shipping name “Biological substances, Category B” must be in letters at least 6 mm high. The proper shipping name, UN number, and the name, address, and telephone number of a person knowledgeable about the shipment must be included on a written document, such as an air waybill or bill of lading, or on the outer packaging. The knowledgeable person should be available during the company’s administrative office hours to provide information about how to respond to emergencies or releases involving the package and appropriate first aid. Finally, we are permitting small amounts of hazardous materials in Packing Groups II or III, not to exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging, to be used to preserve or stabilize the material. Such preservatives are not subject to HMR requirements.

Category B infectious substances prepared in accordance with § 173.199 are excepted from all other HMR requirements except for incident reporting and the requirements in Part 175 of the HMR prohibiting a hazardous material subject to the HMR requirements from being transported in the cabin of a passenger aircraft or the flight deck of any aircraft.

The requirements in § 173.199(d) for used health care products are relocated to § 173.134(b)(12)(ii).

Part 175

Section 175.630. We are adding a new paragraph (c) to this section to require air carriers to inspect packages containing Division 6.2 materials for leakage when they are unloaded. If evidence of leakage is found, the cargo compartment must be disinfected. In response to comments, we are modifying the proposal in this final rule to require air carriers to inspect unit load devices as well as individual packages and packages in overpacks.

IV. Rulemaking Analysis and Notices

A. Statutory/Legal Authority for This Rulemaking

This final rule is published under the following statutory authorities:

1. 49 U.S.C. 5103(b) authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce. This final rule adopts regulations to enhance the safe and secure transportation of infectious substances in intrastate, interstate, and foreign commerce. To this end, as discussed in detail earlier in this preamble, the final rule revises current HMR requirements applicable to infectious substances for classification, packaging, and hazard communication and for offerors and transporters of certain infectious substances to develop and implement security plans.

2. 49 U.S.C. 5120(b) authorizes the Secretary of Transportation to ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with standards adopted by international authorities. This final rule adopts regulations applicable to the transportation of infectious substances in commerce consistent with international standards applicable to such transportation. To this end, as discussed in detail earlier in this preamble, the final rule harmonizes current HMR requirements for infectious substances with the standards adopted for the transportation of

infectious substances in the UN Recommendations, the 2005–2006 ICAO Technical Instructions, and Amendment 32 to the IMDG Code. The continuously increasing amount of hazardous materials transported in international commerce warrants the harmonization of domestic and international requirements to the greatest extent possible. Harmonization serves to facilitate international transportation; at the same time, harmonization ensures the safety of people, property, and the environment by reducing the potential for confusion and misunderstanding that could result if shippers and transporters were required to comply with two or more conflicting sets of regulatory requirements. While the intent of this rulemaking is to align the HMR with international standards, we review and consider each amendment on its own merit based on its overall impact on transportation safety and the economic implications associated with its adoption into the HMR. Our goal is to harmonize without sacrificing the current HMR level of safety and security and without imposing undue burdens on the regulated public. As discussed in detail earlier in this preamble, there are several instances where we elected not to propose adoption of a specific provision of the UN Recommendations or the ICAO Technical Instructions. Further, we are maintaining a number of current exceptions for domestic transportation to minimize the compliance burden on the regulated community.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. This final rule is not considered significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). This final rule will reduce transportation costs for shipments of certain infectious substances. We estimate annual cost savings of \$3.85 billion. Additional benefits resulting from the adoption of the amendments in this final rule include enhanced transportation safety, security, and efficiency resulting from consistent domestic and international transportation requirements. The final rule will result in new costs of compliance related to the development and implementation of transportation security plans for persons who ship USDA-regulated select agents and toxins. A regulatory evaluation for this

final rule is in the public docket for this rulemaking.

This final rule relaxes requirements for transporting Category B infectious substances. Currently, many of these infectious substances must be shipped in appropriately marked and labeled UN specification packagings and accompanied by shipping papers and emergency response information; these infectious substances are also subject to incident reporting requirements. Under this final rule, Category B infectious substances may be shipped in non-specification packagings, marked with the appropriate UN number. However, they are excepted from labeling and shipping documentation requirements. Category B infectious substances are also excepted from incident reporting requirements, except for shipments by aircraft.

We estimate that shippers of most infectious substances will realize an average cost savings of \$77 per shipment. There are no published data on the number of infectious substances shipments transported each year. Industry estimates suggest about 160 million patient samples are shipped outside of a local area each year (ground transportation of infectious substances is excepted from most HMR requirements). A shipment may contain from one to 20 test tubes or primary containers, with an average of about 3 primary containers per package. Thus, the number of shipments transported annually by air may total 53 million. Under this final rule, most of these shipments will realize a cost savings of \$77, for a total annual cost savings of \$3.85 billion (50 million shipments × \$77/shipment).

This final rule will also result in significant non-monetized benefits. The final rule harmonizes the requirements in the HMR for transporting infectious substances with international standards in the UN Recommendations, the ICAO Technical Instructions, and the International Maritime Dangerous Goods Code. Harmonization of requirements in the HMR with international standards will allow us to avoid inconsistencies between the regulations, thereby facilitating rapid and efficient transportation of infectious substances across national or international borders, which is critical to public health. Moreover, harmonized regulations reduce the potential for misunderstanding and confusion and, thus, enhance safety.

Estimating the security benefits of this final rule is difficult. In the end, when security measures are evaluated, an element of judgment is required to determine whether the costs of the

measures are justified by the benefits that will accrue. We believe the relatively small costs imposed on individual companies to comply with the security plan requirements are more than offset by the benefits if there is a finite chance that these measures might avert a successful attack. Most entities handling USDA-regulated select agents and toxins likely have already implemented security measures similar to those required under the HMR. The security requirements are not onerous. They are prudent, common sense security measures in line with public expectations about the need to take action to protect hazardous materials shipments from terrorist acts.

C. 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 (49 U.S.C. 5125(b)) preempting State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

- (1) The designation, description, and classification of hazardous materials;
- (2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;
- (3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;
- (4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or
- (5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This final rule addresses covered subject items (1), (2), (3), (4), and (5) described above and preempts State, local, and Indian tribe requirements not meeting the “substantively the same” standard. This final rule is necessary to harmonize domestic regulations for the

transportation of infectious substances with international standards.

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

D. 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"). Because this proposed rule does not have tribal implications and does not impose direct compliance costs, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (5 U.S.C. 601–611) requires each agency to analyze proposed regulations and assess their impact on small businesses and other small entities to determine whether the proposed rule is expected to have a significant impact on a substantial number of small entities. A regulatory evaluation for this NPRM, which includes a detailed small business impact analysis, is in the public docket for this rulemaking.

Businesses likely to be affected by the provisions of this final rule are the more than 441,000 establishments comprising North American Industrial Classification System Major Groups 32, 48, 54, and 62, including offices and clinics of doctors of medicine, dentists, doctors of osteopathy, chiropractors, optometrists, podiatrists, and health practitioners; nursing and personal care facilities; hospitals; medical and dental laboratories; and patients. For purposes of the small business impact analysis, the definition of "small business" has the same meaning as under the Small Business Act. The majority of the businesses likely to be affected by the provisions of this final rule are small businesses (from 68% of general medical and surgical hospitals to nearly 100% of doctors' offices and research laboratories).

For the most part, affected businesses will incur no increased costs to comply with the provisions of this final rule;

indeed, the provisions of this final rule will reduce overall transportation costs for most of these entities. Manufacturers and distributors of packages intended for the transportation of infectious substances will incur costs associated with retaining copies of filling and closure instructions for such packages; we estimate the cost per company will be about \$750/year. In addition, air carriers will incur increased costs associated with new cargo inspection requirements; we estimate these costs would amount to \$1.34 per package of infectious substances transported. Finally, the final rule imposes new costs on the regulated industry for shipments of select agents and toxins regulated by USDA; we estimate these costs would amount to \$1,125 per company to develop a security plan and a subsequent annual cost of \$225 per entity to update and maintain the security plan. The annual costs attributed to the provisions of 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.

Benefits resulting from the adoption of the amendments in this final rule include reduced transportation costs for shipments of certain infectious substances and enhanced transportation safety, security, and efficiency resulting from consistent domestic and international transportation requirements. For example, companies shipping infectious substances can expect to experience an average cost savings of \$77 per shipment as packaging costs decrease from between \$88.30–\$143.78 to between \$29.85–\$48.07 as a result of new packaging requirements for Category B infectious substances and \$1.90 per shipment as a result of revised hazard communication requirements for Category B infectious substances. In addition, the final rule will result in enhanced security for the transportation of select agents. Finally, the final rule removes inconsistencies between the HMR and international transportation standards applicable to the transportation of infectious substances, thereby facilitating efficient transportation across national and international borders and reducing the potential for misunderstanding and confusion in applying the regulatory requirements.

Based on the above analysis, I certify that while this final rule will affect a significant number of small entities it will not have a significant economic impact on a substantial number of small entities.

This final rule has been developed in accordance with Executive Order 13272 ("Proper Consideration of Small Entities in Agency Rulemaking") and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure potential impacts of draft rules on small entities are properly considered.

F. Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It will not result in costs of \$120.7 million or more, in the aggregate, to any of the following: State, local, or Native American tribal governments, or the private sector.

G. Paperwork Reduction Act

This final rule does not impose any new information collection requirements.

H. 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 number contained in the heading of this document may be used to cross-reference this action with the Unified Agenda.

I. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4347), requires Federal agencies to consider the consequences of major federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment. There are no significant environmental impacts associated with this final rule. We are adopting changes to certain HMR requirements for the transportation of infectious substances in order to promote safer transportation practices, facilitate international commerce, and make these requirements compatible with new international standards regarding the transportation of infectious substances.

J. Privacy Act

Any comments received into any of our dockets may be searched electronically by the name of the individual submitting the comments (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11,

2000 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://dms.dot.gov>.

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, Incorporation by reference, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 175

Air carriers, Hazardous materials transportation, Incorporation by

reference, Radioactive materials, Reporting and recordkeeping requirements.

■ In consideration of the foregoing, we are amending 49 CFR parts 171, 172, 173, and 175 as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITION

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101-5127, 44701; 49 CFR 1.45 and 1.53; Pub. L. 101-410 section 4 (28 U.S.C. 2461 note); Pub. L. 104-134 section 31001.

§ 171.8 [Amended]

■ 2. In § 171.8, the definition for “Risk Group” is removed.

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

■ 3. The authority citation for part 172 continues to read as follows:

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

■ 4. In § 172.101, in the Hazardous Materials Table, the following changes are made:

- a. The entry “Diagnostic specimen” is removed.
- b. The entry “Biological substance, Category B” is added in appropriate alphabetic order.
- c. The entries “Infectious substances, affecting animals *only*,” “Infectious substances, affecting humans,” and “Regulated medical waste, n.o.s.” are revised.

The additions and revisions read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

* * * * *

§ 172.102 [Amended]

■ 5. In § 172.102, in paragraph (c)(2), Special Provision A81 is removed.

■ 6. In § 172.200, paragraph (b)(4) is added to read as follows:

§ 172.200 Applicability.

* * * * *

(b) * * *

(4) Category B infectious substances prepared in accordance with § 173.199.

■ 7. In § 172.203, in paragraph (k) introductory text a sentence is added after the last sentence to read as follows:

§ 172.203 Additional description requirements.

* * * * *

(k) * * * A material classed as Division 6.2 and assigned identification number UN 2814 or 2900 because it is suspected to contain an unknown Category A infectious substance must have the words "suspected Category A infectious substance" entered in parentheses in place of the technical name as part of the proper shipping description.

* * * * *

■ 8. In § 172.301, paragraph (b) is revised to read as follows.

§ 172.301 General marking requirements for non-bulk packagings.

* * * * *

(b) Technical names. In addition to the marking required by paragraph (a) of this section, each non-bulk packaging containing a hazardous material subject to the provisions of § 172.203(k) of this part, except for a Division 6.2 material, must be marked with the technical name in parentheses in association with the proper shipping name in accordance with the requirements and exceptions specified for display of technical descriptions on shipping papers in § 172.203(k) of this part. A technical name should not be marked on the outer package of a Division 6.2 material.

* * * * *

■ 9. In § 172.800, paragraph (b)(6) is revised to read as follows:

§ 172.800 Purpose and applicability.

* * * * *

(b) * * *

(6) A select agent or toxin regulated by the Centers for Disease Control and Prevention under 42 CFR part 73 or, by April 1, 2007, a select agent or toxin regulated by the United States Department of Agriculture under 9 CFR part 121; or

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 9. 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.

■ 10. In § 173.6, paragraph (a)(4) is revised to read as follows:

§ 173.6 Materials of trade exceptions.

(a) * * *

(4) A Division 6.2 material, other than a Category A infectious substance, contained in human or animal samples (including, but not limited to, secret, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste. The material must be contained in a combination packaging. For liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. For solids, liquids, and sharps, the outer packaging must be a strong, tight packaging securely closed and secured against movement, including relative motion between packages, within the vehicle on which it is being transported.

(i) For other than a regulated medical waste, the amount of Division 6.2 material in a combination packaging must conform to the following limitations:

(A) One or more inner packagings, each of which may not contain more than 0.5 kg (1.1 lbs) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs) or 4 L (1 gallon); or

(B) A single inner packaging containing not more than 16 kg (35.2 lbs) 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, each of which may not contain more than 4 kg (8.8 lbs) or 4 L (1 gallon), and an outer packaging containing not more than 16 kg (35.2 lbs) or 16 L (4.2 gallons).

* * * * *

■ 11. In § 173.24a, paragraph (c)(2) is revised to read as follows:

§ 173.24a Additional general requirements for non-bulk packagings and packages.

* * * * *

(c) * * *

(2) A packaging containing inner packagings of Division 6.2 materials may not contain other hazardous materials except—

(i) Refrigerants, such as dry ice or liquid nitrogen, as authorized under the HMR;

(ii) Anticoagulants used to stabilize blood or plasma; or

(iii) Small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II or III used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging. The maximum quantity in an outer package, including a hazardous material used to preserve or stabilize a sample, may not exceed 4 L (1 gallon) or 4 kg (8.8 pounds). Such preservatives are not subject to the requirements of this subchapter.

* * * * *

■ 12. In § 173.134, paragraph (a) introductory text and paragraphs (a)(1), through (a)(5) are revised; paragraph (a)(6) is removed; paragraphs (a)(7), (a)(8), and (a)(9) are redesignated paragraphs (a)(6), (a)(7), and (a)(8) respectively, and paragraphs (b), (c)(1)(ii), and (c)(2) are revised to read as follows:

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

(a) Definitions and classification criteria. For the purposes of this subchapter, the following definitions and classification criteria apply to Division 6.2 materials.

(1) Division 6.2 (Infectious substance) means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN 3373, or UN 3291 as appropriate, and must be assigned to one of the following categories:

(i) Category A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. A Category A infectious

substance must be assigned to identification number UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

(ii) *Category B*: An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes. A Category B infectious substance must be described as "Biological substance, Category B" and assigned identification number UN 3373. This does not include regulated medical waste, which must be assigned identification number UN 3291.

(2) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals. A *biological product* includes a material subject to regulation under 42 U.S.C. 262 or 21 U.S.C. 151–159. Unless otherwise excepted, a *biological product* known or reasonably expected to contain a pathogen that meets the definition of a Category A or B infectious substance must be assigned the identification number UN 2814, UN 2900, or UN 3373, as appropriate.

(3) *Culture* means an infectious substance containing a pathogen that is intentionally propagated. *Culture* does not include a human or animal patient specimen as defined in paragraph (a)(4) of this section.

(4) *Patient specimen* means human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. *Patient specimen* includes excreta, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture bottles).

(5) *Regulated medical waste* means a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products.

Regulated medical waste is assigned to UN 3291, except for *regulated medical waste* containing a Category A infectious substance, which must be classed as a Division 6.2 material, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

* * * * *

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

(1) A material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals.

(2) Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic elements.

(3) A material containing microorganisms that are non-pathogenic to humans or animals.

(4) A material containing pathogens that have been neutralized or inactivated such that they no longer pose a health risk.

(5) A material with a low probability of containing an infectious substance, or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include: Foodstuffs; environmental samples, such as water or a sample of dust or mold; and substances that have been treated so that the pathogens have been neutralized or deactivated, such as a material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance.

(6) A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture.

(7) Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; 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 (42 U.S.C. 264–272) and/or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 *et seq.*).

(8) Blood, blood plasma, and blood components 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 as a Category A or Category B infectious substance in accordance with § 173.196 or § 173.199, as appropriate.

(9) Dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material.

(10) A Division 6.2 material, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a biological product, when such materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. 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 the human or animal sample 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.

(11) A human or animal sample (including, but not limited to, secretions, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

(12) Laundry and medical equipment and used health care products, as follows:

(i) 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.

(ii) Used health care products not conforming to the requirements in 29 CFR 1910.1030 and being returned to the manufacturer or the manufacturer's designee are excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this paragraph (b)(12). For purposes of this paragraph, a health care product is used when it has been removed from its original packaging. Used health care products contaminated with or suspected of contamination with a Category A infectious substance may not be transported under the provisions of this paragraph.

(A) 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).

(B) 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).

(C) 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.

(D) Each person who offers or transports a used health care product under the provisions of this paragraph must know about the requirements of this paragraph.

(13) 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.

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

(15) 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 Category B infectious substance must be shipped in a packaging conforming to the provisions of § 173.24.

(ii) Forensic material known or suspected to contain a Category A infectious substance or an infectious substance listed as a select agent in 42 CFR Part 73 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.

(16) Agricultural products and food as defined in the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 332 *et seq.*).

(c) * * *

(1) * * *

(i) * * *

(ii) The specific packaging requirements of § 173.197, 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, provided the material does not include a waste concentrated stock culture of an infectious substance. Sharps containers must be securely closed to prevent leaks or punctures.

(2) A waste stock or culture of a Category B 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 in a vehicle used exclusively to transport 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. Sharps containers must

be securely closed to prevent leaks or punctures.

* * * * *

■ 13. In § 173.196, the section title and paragraphs (a) introductory text, (a)(2), (a)(3), and (b) are revised, to read as follows.

§ 173.196 Category A infectious substances.

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

* * * * *

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

(3) A rigid outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must measure not less than 100 mm (3.9 inches) at its smallest overall external dimension.

* * * * *

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

(1) *Infectious substances shipped at ambient temperatures or higher.* Primary receptacles must be made 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, paraffin sealing tape, or manufactured locking closure. Lyophilized substances may also be transported in primary receptacles that are flame-sealed with glass ampoules or rubber-stoppered glass vials fitted with metal seals.

(2) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice, dry ice, or other refrigerant must be placed around 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 outer packaging or overpack must be leakproof. If dry ice is used, the outer packaging or overpack 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 transport by aircraft to which they could be subjected if refrigeration were lost.

(3) *Infectious substances shipped in liquid nitrogen.* 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 transport by aircraft to which they could be subjected if refrigeration were lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks 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.

* * * * *

■ 14. In § 173.197, paragraphs (a), (b), (d)(1)(iv), (d)(1)(vi), (d)(2)(iii), (d)(3)(vi), (e)(2) and (e)(3) introductory paragraph are revised to read as follows:

§ 173.197 Regulated medical waste.

(a) *General provisions.* Non-bulk packagings, Large Packagings, and non-specification 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 provided in § 173.134(c) of this subpart, non-bulk packagings for regulated medical waste must be UN standard packagings conforming to the requirements of Part 178 of this subchapter at the Packing Group II performance level. A non-bulk packaging used as a sharps container 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. Sharps containers must be securely closed to prevent leaks or punctures in conformance with the instructions provided by the packaging manufacturer in accordance with § 178.2(c) of this subchapter.

* * * * *

(d) * * *

(1) * * *

(iv) Untreated concentrated stock cultures of infectious substances containing Category A materials may not be transported in a Cart or BOP.

* * * * *

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated concentrated stock cultures of infectious substances containing Category B infectious substances; 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) * * *

(iii) Each Cart must be capable of meeting the requirements of § 178.810 (drop test) at the Packing Group II performance level.

* * * * *

(3) * * *

(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated concentrated stock cultures of infectious substances containing Category B infectious substances, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as required in paragraph (d)(3)(v) of this section.

* * * * *

(e) * * *

(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 provisions of subpart B of this part. 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 must be securely closed to prevent leaks or punctures in conformance with instructions provided by the packaging manufacturer. Each sharps container exceeding 76 L (20 gallons) in volume must be capable of passing the performance tests in Part 178, subpart M, of this subchapter at the Packing Group II performance level. A

sharps container may be reused only if it conforms to the following criteria:

* * * * *

15. In § 173.199, the section title and paragraphs (a), (b) introductory text, (b)(1), (b)(2), (b)(5), and (c), (d), and (e) are revised, to read as follows:

§ 173.199 Category B infectious substances.

(a) *Category B infectious substances.* Except as provided in this paragraph (a), Category B infectious substances are excepted from all other requirements of this subchapter when offered for transportation or transported in accordance with this section. Category B infectious substances offered for transportation or transported under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter and to the requirements in § 175.85 of this subchapter concerning cargo location. Except as provided in paragraph (a)(9) of this section, a Category B infectious substance 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) A Category B infectious substance must be packaged in a triple packaging consisting of a primary receptacle, a secondary packaging, and a rigid 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 rigid 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 designed, constructed, maintained, filled, its contents limited, and closed so that under conditions normally encountered in transportation, including removal from a pallet or overpack for subsequent handling, there will be no release of hazardous material into the environment. Package effectiveness must not be substantially reduced for minimum and maximum temperatures, changes in humidity and pressure, and shocks, loadings and vibrations normally encountered during transportation. The packaging must be capable of successfully passing the drop tests in §§ 178.609(d) and (h) of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop

tests, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches).

(5) The following mark must be displayed on the outer packaging on a background of contrasting color. The width of the line must be at least 2 mm (0.08 inches) and the letters and numbers must be at least 6 mm (0.24 inches) high. The size of the mark must be such that no side of the diamond is less than 50 mm (1.97 inches) in length. The proper shipping name "Biological substances, Category B" must be marked on the outer packaging adjacent to the diamond-shaped mark in letters that are at least 6 mm (0.24 inches) high.



(6) When packages are placed in an overpack, the package markings required by this section must be either clearly visible or reproduced on the outside of the overpack.

(7) The name and telephone number of a person who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or has immediate access to a person who possesses such knowledge and information, must be included on a written document (such as an air waybill or bill of lading) or on the outer packaging.

(8) For transportation by aircraft, each package, overpack, pallet, or unit load device containing a Category B infectious substance must be inspected for leakage when it is unloaded from the aircraft. If evidence of leakage is found, the cargo compartment in which the package, overpack, pallet, or unit load device was transported must be disinfected. Disinfection may be by any means that will make the material released ineffective at transmitting disease.

(9) A packaging containing inner packagings of Category B infectious

substances may not contain other hazardous materials except—

(i) Refrigerants, such as dry ice or liquid nitrogen, as authorized under paragraph (d) of this section;

(ii) Anticoagulants used to stabilize blood or plasma; or

(iii) Small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging. Such preservatives are not subject to the requirements of this subchapter.

(10) Clear instructions on filling and closing a packaging used to transport a Category B infectious substance must be provided by the packaging manufacturer and subsequent distributors to the consignor or person who prepares the package to enable the package to be correctly prepared for transport. A copy or electronic image of these instructions must be retained by the manufacturer and subsequent distributors for at least one year from the date of issuance, and made available for inspection by a Federal or state government representative upon request. Packagings must be filled and closed in accordance with the information provided by the packaging manufacturer or subsequent distributor.

(b) *Liquid Category B infectious substances.* Liquid Category B infectious substances must be packaged in conformance with the following provisions:

(1) The primary receptacle must be leakproof.

(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 either individually wrapped or separated to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles and not compromise the integrity of the cushioning material or the outer packaging.

* * * * *

(5) For shipments by aircraft, the maximum quantity contained in each primary receptacle, including any material used to stabilize or prevent degradation of the sample, may not exceed 1 L (34 ounces), and the maximum quantity contained in each outer packaging, including any material used to stabilize or prevent degradation of the samples, may not exceed 4 L (1 gallon). The outer packaging limitation does not include ice, dry ice, or liquid

nitrogen when used to maintain the integrity of the material.

(c) *Solid Category B infectious substances.* Solid Category B infectious substances 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.

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

(3) The secondary packaging must be siftproof.

(4) If residual liquid may be present in the primary receptacle during transportation, then the material must be transported in accordance with requirements in paragraph (b) of this section. A solid material that may become liquid during transportation must be transported in accordance with paragraph (b) of this section.

(5) Except for packages containing body parts, organs, or whole bodies, for shipment by aircraft, the outer packaging may not contain more than 4 kg (8.8 pounds), including any material used to stabilize or prevent degradation of the samples. The outer packaging limitation does not include ice, dry ice, or liquid nitrogen when used to maintain the integrity of the material.

(d) *Refrigerated or frozen specimens (ice, dry ice, and liquid nitrogen).* In addition to complying with the requirements in this paragraph (d), dry ice and liquid nitrogen must be offered for transportation or transported in accordance with the applicable requirements of this subchapter.

(1) Ice or dry ice must be placed outside the secondary packaging or in an overpack. 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 or must have a leakproof liner. 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 secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft they could be subjected to if refrigeration were lost, and sufficient absorbent material must be provided to absorb all liquid, including melted ice.

(2) The package is marked "Carbon dioxide, solid" or "Dry ice" and an

indication that the material being refrigerated is used for diagnostic treatment purposes (e.g., frozen medical specimens).

(e) *Training.* Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section.

PART 175—CARRIAGE BY AIRCRAFT

■ 16. The authority citation for part 175 continues to read as follows:

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

■ 17. In § 175.630, the section heading is revised and paragraph (c) is added to read as follows:

§ 175.630 Special Requirements for Division 6.1 (poisonous) material and Division 6.2 (infectious substances) materials.

* * * * *

(c) When unloaded from the aircraft, each package, overpack, pallet, or unit load device containing a Division 6.2 material must be inspected for signs of

leakage. If evidence of leakage is found, the cargo compartment in which the package, overpack, or unit load device was transported must be disinfected. Disinfection may be by any means that will make the material released ineffective at transmitting disease.

Issued in Washington, DC, on May 24, 2006, under the authority delegated in 49 CFR part 1.

Brigham A. McCown,
Acting Administrator.

[FR Doc. 06–4992 Filed 6–1–06; 8:45 am]

BILLING CODE 4910–60–P