

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****49 CFR Parts 171, 172, 173, 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: Notice of proposed rulemaking (NPRM).

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

DATES: Comments must be received by July 18, 2005.

ADDRESSES: You may submit comments by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Web Site: <http://dms.dot.gov>. Follow the instructions for submitting comments on the DOT electronic docket site. You may view the public docket through the Internet at <http://dms.dot.gov> or in person at the Docket Management System office at the above address.

Fax: 1-202-493-2251

Mail: Docket Management System, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-0001.

Hand Delivery: To the Dockets Management System; Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name (Pipeline and Hazardous Materials Safety Administration) and docket number (PHMSA-2004-16895 (HM-226A)) or the Regulatory Identification Number (RIN) for this notice at the beginning of your

comments. You should submit two copies of your comments if you submit them by mail. If you wish to receive confirmation that we received your comments, you must include a self-addressed stamped postcard. Note that all comments received will be posted without change to "<http://dms.dot.gov>", including any personal information provided, and will be accessible to Internet users. Please see the Privacy Act section of this document.

FOR FURTHER INFORMATION CONTACT:

Eileen Edmonson or Deborah Boothe, Office of Hazardous Materials Standards, (202) 366-8553, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

SUPPLEMENTARY INFORMATION:**I. Background**

On August 14, 2002, the Research and Special Programs Administration (RSPA), the predecessor agency to the Pipeline and Hazardous Materials Safety Administration (PHMSA), published a final rule revising the requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of infectious substances, including regulated medical waste (67 FR 53118). The final rule made the following changes to the HMR:

- Adopted new classification criteria for infectious substances based on defining criteria developed by the World Health Organization (WHO) and consistent with standards contained in the 12th Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and the 2003-2004 Edition of the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions).

- Revised packaging requirements for Division 6.2 materials for consistency with international performance standards.

- Eliminated an exception from requirements in the HMR for diagnostic specimens and adopted certain packaging and hazard communication requirements for these materials. Diagnostic specimens transported by private or contract carriers in motor vehicles used exclusively for diagnostic specimens continue to be excepted from most requirements in the HMR.

- Modified an exception from requirements in the HMR for biological products, limiting the exception to biological products licensed for use under current Food and Drug

Administration (FDA) or U.S. Department of Agriculture (USDA) regulations.

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

- Established new hazard communication requirements for shipments of Division 6.2 materials.

The requirements in the August 14, 2002 final rule became effective on February 14, 2003.

II. Issues Related to Current Requirements

Our August 14, 2002 final rule adopted a risk-group-based classification system for infectious substances based on criteria in the UN Recommendations. The final rule requires 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 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.

The requirements adopted for the UN Recommendations establish a two-tiered

classification system for Division 6.2 materials—Category A and Category B. A Category A infectious substance poses a higher degree of risk than a Category B infectious substance. A Category A material is an infectious substance that is transported in a form that is 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 UN 2814 (for substances that cause disease in humans or in both humans and animals) or UN 2900 (for substances that cause disease in animals only). The following are examples of Category A infectious substances. Please note this list is not all inclusive and is provided only as guidance.

UN number 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 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 Russian spring-summer encephalitis virus (cultures only) Sabia virus Shigella dysenteriae type I (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus

UN number and proper shipping name	Micro-organism
UN 2900: Infectious substances affecting animals only	Venezuelan equine encephalitis virus 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)

Under the UN Recommendations, Category A infectious substances are packaged in UN specification packagings that consist of a watertight primary receptacle or receptacles; a watertight secondary packaging; for liquid materials, absorbent material in sufficient quantity to absorb the entire contents; and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. The completed packaging must pass specified performance tests, including a drop test and a water-spray test, and must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The completed packaging must also be capable of withstanding, without leakage, temperatures in the range of -40 °C to +55 °C (-40 °F to 131 °F). The completed package must be labeled with a Division 6.2 label and must be accompanied by appropriate shipping documentation. The packaging specified for Category A infectious substances is consistent with the packaging currently required for infectious substances assigned to UN 2814 or UN 2900.

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.

The Category A and B designations developed for purposes of transportation are different from the Category A and B designations for agents of bioterrorism developed by the Centers for Disease Control and Prevention (CDC) and the National

Institutes of Health (NIH). The criteria for inclusion in these categories differ, and, although there is some overlap, the lists should not be confused. It is extremely important that persons offering infectious materials for transportation in commerce assign infectious substances to the appropriate category to avoid inappropriate packaging for the materials.

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 names “Diagnostic Specimen” and “Clinical Specimen” in the 13th Edition of the UN Recommendations and in the 2005–2006 ICAO Technical Instructions, and adoption of the proper shipping name “Diagnostic specimen” in the HMR have 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.

Under the UN Recommendations, a Category B infectious substance is packaged in a packaging consisting of a leakproof primary receptacle, a leakproof secondary packaging, and a rigid outer packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches). The packaging must be of good quality and strong enough to withstand the shocks and loadings normally encountered during transportation. For liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of the primary receptacle or receptacles. The primary or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of 95 kPa. The packaging must be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transportation by vibration or changes in temperature, humidity, or pressure. The completed packaging must be capable of passing a 1.2-meter (3.9 feet) drop test. The package must be marked with a diamond-shaped marking containing the identification number “UN 3373” and with the proper shipping name “Biological substance, Category B.” The minimum size for the diamond-shaped mark includes sides at least 50 mm (1.97 inches) long, and letters and numbers at least 6 mm (0.24 inches) high. Under the UN Recommendations, shipments of Category B infectious substances are not

subject to any other transportation requirements.

The 2005–2006 ICAO Technical Instructions, which are based in part on the UN Recommendations, include additional requirements for Category B infectious substances. Specifically, the ICAO Technical Instructions 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, or on the package.

Representatives of the United States worked closely with the UN Committee of Experts and the ICAO Dangerous Goods Panel to develop the revised requirements for transporting infectious substances. The new requirements are based on a scientific evaluation of the real risks that these materials pose in transportation. Category B infectious substances pose a reduced risk of infection upon exposure based on the way they are transmitted (route of infection) and the number of pathogens required to initiate an infection. Certain infectious substances previously assigned to Risk Group 2 or 3 substances are now assigned to Category B infectious substances and are subject to less stringent regulatory requirements. The Category B packaging provides triple barriers and absorbent and cushioning materials that are designed to prevent leakage of the material during transportation. We believe that the regulations developed for the 13th and 14th Revised Editions of the UN Recommendations provide a less confusing and more appropriate regulatory system than the current risk-group-based system. Therefore, in this NPRM, we are proposing to harmonize the HMR requirements for the transportation of infectious substances with those adopted or expected to be adopted for the UN Recommendations and the ICAO Technical Instructions.

Specific regulatory proposals are discussed in the “Section-by-Section Review” section of this preamble.

III. Category A Versus Risk Group 4 Classification

As indicated above, the HMR currently require Division 6.2 materials to be assigned to one of four risk groups based on the degree of risk associated with laboratory manipulation of the pathogen. A Risk Group 4 pathogen is one that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available. A Category A material is an

infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. As the guidance earlier in this document suggests, this new definition may include cultures of materials that previously were considered Risk Group 2 and 3 materials. The transportation requirements for Category A infectious substances are identical to current requirements under both the HMR and the UN Recommendations for Risk Group 4 infectious substances.

The HMR currently provide for exceptions from certain regulatory requirements for Risk Group 2 or 3 infectious substances; however, these exceptions may not be used for Risk Group 4 materials. For example, the HMR currently permit diagnostic specimens, biological products, and regulated medical waste (RMW) that contain Risk Group 2 or 3 infectious substances to be transported as materials of trade (MOTS) in accordance with § 173.6. The MOTS exception may not be used to transport Risk Group 4 materials. In this NPRM, we propose to limit exceptions authorized for the transportation of infectious substances to Category B materials; thus, Category A materials could not be shipped as MOTS. We recognize that this approach somewhat narrows the applicability of the transportation exceptions that are currently permitted under the HMR. In particular, we note that, as proposed in this NPRM, RMW that contains a Category A infectious substance must be transported in accordance with requirements applicable to UN 2814 (infectious substance affecting humans) or UN 2900 (infectious substance affecting animals only) rather than UN 3291 (regulated medical waste). We believe the proposed amendments accurately address the risks posed by these materials; however, we invite commenters to address the transportation impacts, if any, of the proposed revisions.

IV. Notification to Pilot-in-Command

As noted earlier, the proposals in this NPRM are consistent with standards adopted by the UN and ICAO. A major issue associated with ICAO’s adoption of the provisions applicable to infectious substances in the 13th Revised Edition of the UN Recommendations was whether or not to require notification to the pilot-in-command (NOPIC) of an aircraft of the presence of Category B infectious substances as cargo on board the aircraft. Under the standards adopted for the UN Recommendations, Category

B infectious substances are not accompanied by shipping papers nor must their packages be labeled. The hazard communication required for a package containing a Category B infectious substance is a package marking consisting of “UN 3373” in a square-on-point configuration and the words “Biological substance, Category B” in association with the UN number. ICAO adopted additional hazard communication requirements for Category B infectious substances. Specifically, the ICAO Technical Instructions 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) or on the package itself. As noted above, we propose to adopt the ICAO requirements into the HMR for air transportation.

Generally, a 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.

ICAO narrowly decided against requiring a NOPIC for shipments of Category B infectious substances for the 2005–2006 Edition of the ICAO Technical Instructions. The ICAO vote on the issue was evenly split; an equal number supported a requirement for a NOPIC for Category B infectious substances as opposed to the requirement. 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. Consistent with the ICAO decision, this

NPRM does not propose to require a NOPIC for Category B infectious substances. However, we invite commenters to address this issue. Should the HMR require a NOPIC for shipments of Category B infectious substances? What would be the benefits or adverse impacts of such a requirement?

V. Transportation of Unknown or Suspected Infectious Substances

The public health community is frequently confronted with outbreaks of disease of unknown etiology and must quickly transport specimens for identification and diagnosis. This rulemaking proposes that, generally, routine samples that are unlikely to contain an infectious substance or where the pathogenicity of the infectious substance is at a level naturally encountered in the environment that will not cause disease when exposure to it occurs may be transported as non-regulated materials. In most other cases, this rulemaking proposes to permit unknown samples shipped for analysis and diagnosis to 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 NPRM proposes to require an indication on shipping papers that the sample contains a Category A infectious material, as follows—"Infectious substances, affecting humans (suspected Category A infectious substance), 6.2, UN 2814". 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.

VI. Security Requirements for Select Agents

Currently, persons who offer for transportation or transport certain infectious substances in commerce must develop and implement security plans

in accordance with Subpart I of Part 172 of the HMR. Specific measures implemented as part of the plan may vary commensurate with the level of threat at a particular time. At a minimum, the security plan must address personnel security, unauthorized access, and en route security. For personnel security, the plan must include measures to confirm information provided by job applicants for positions that involve access to and handling of the hazardous materials covered by the plan. For unauthorized access, the plan must include measures to address the risk that unauthorized persons may gain access to materials or transport conveyances being prepared for transportation. For en route security, the plan must include measures to address security risks during transportation, including shipments stored temporarily en route to their destinations.

For infectious substances, the security plan requirements apply to shipments of select agents and toxins regulated by CDC under 42 CFR Part 73. The CDC regulations identify select agents and toxins affecting humans ("HHS Select Agents and Toxins") and select agents and toxins affecting both humans and animals ("Overlap Select Agents and Toxins"). The USDA regulations at 9 CFR Part 121 identify select agents and toxins affecting animals, in addition to the Overlap Select Agents and Toxins that are also listed in the CDC regulations. USDA regulations at 7 CFR Part 331 identify agents and toxins affecting plants. Select agents and toxins affecting animals only are not currently subject to the security plan requirements. Biological agents and toxins affecting plants only do not meet the definition of an infectious substance under the HMR.

CDC and USDA regulate select agents and toxins because they have the potential to pose a severe threat to the public health and safety. Select agents and toxins affecting animals could be used to compromise public health; therefore, in this NPRM we propose to add the select agents and toxins listed in 9 CFR Part 121 to the list of hazardous materials for which security plans are required. As proposed, persons who offer or transport any of the materials regulated under 9 CFR Part 121 would be required to develop and implement security plans that conform to HMR requirements. We propose to provide six months from the effective date of a final rule for shippers and carriers to come into compliance with this new requirement.

We invite commenters to address whether we should also require persons

who offer or transport select agents and toxins that have been found to pose a severe threat to plant health or plant products, regulated by USDA under 7 CFR Part 331, to develop and implement transportation security plans. Such materials could also be used illegitimately to compromise public health.

VII. Sharps Containers

There appears to be some confusion in the regulated community about HMR requirements applicable to sharps containers. The current requirements appear in several places in the regulations. For non-bulk shipments, a sharps container must be a UN specification packaging that is puncture resistant for sharps and sharps with residual fluid as demonstrated by conformance to the design and test requirements in Subpart M of Part 178 at the Packing Group II performance level. A sharps container that conforms to these requirements need not be placed in an outer packaging for transport. 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)).

Our enforcement experience indicates that the closures currently being used for sharps containers may not adequately assure that no contents will be released during transportation. Therefore, in this NPRM, we proposed to add specific closure requirements in a number of sections applicable to the transportation of RMW, including sharps. In addition, we invite commenters to consider whether the requirements for sharps containers should be modified. In this regard, we note that certain sharps containers are regulated as medical devices subject to pre-market review by FDA. FDA's pre-market review seeks primarily to address sharps containment in hospital and laboratory settings, not for transportation. It is our understanding, therefore, that sharps containers cleared or approved by FDA may not meet the HMR requirements in §§ 173.197(b) and 173.134(c). For example, FDA reviews marketing applications for sharps containers to determine, among other things, whether they are leak resistant on the sides and bottoms and closures are leak resistant. This is a lesser standard than the leakproofness standard established in the HMR. We ask 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. For example, we could permit FDA-cleared or -approved sharps containers to be used for the transportation of sharps provided such containers are placed inside a leakproof outer packaging.

VIII. Incident Reporting Since February 14, 2003

Under the final rule adopted under Docket HM-226, effective February 14, 2003, air carriers are required to report incidents involving diagnostic specimens in accordance with the incident reporting requirements in §§ 171.15 and 171.16. We conducted a review of incidents involving diagnostic specimens in air transportation. We found that 133 air transport incidents were reported between March and June 2004. Prior to March 2004, carriers reported very few incidents. (A chart summarizing the reported incidents and a detailed listing of the incident reports is included in the docket for this rulemaking.) An analysis of the detailed incident reports indicates that in almost all cases the packages that leaked were not prepared in accordance with the requirements of § 173.199. For example, many of the reported incidents appear to have resulted from improper closure

of either the primary receptacle or the secondary packaging. Other packagings involved in reported incidents did not include absorbent or cushioning material. Our analysis does not show a trend in package failures that would indicate a problem with the adequacy of the packaging currently authorized by the HMR for the transportation of diagnostic specimens and proposed in this NPRM to be authorized for the transportation of Category B infectious substances. Rather, our analysis indicates that some shippers do not understand the regulatory requirements in § 173.199. To address this problem, in this NPRM we propose to require the manufacturer and subsequent distributors of packagings authorized for the transportation of Category B infectious substances under § 173.199 to provide clear instructions on filling, preparing, and closing the packaging to the consignor or the person who prepares the package for transportation.

In this regard, we note that a number of testing laboratories provide the packaging for patients or health care professionals to use in transporting patient samples for testing and diagnosis. Under this NPRM, the proposed requirement to provide clear filling and closure instructions would apply to such testing laboratories as "subsequent distributors" of the packaging. It is also important to note that selection of an appropriate packaging for the transportation of a hazardous material is a regulated pre-transportation function under the HMR. Thus, the entity providing the packaging could be subject to enforcement action as an offeror of the infectious substance if the packaging does not comply with applicable HMR requirements.

We have prepared a guidance document addressing the current requirements in the HMR for proper classification and packaging for diagnostic specimens which is available from our Office of Hazardous Materials Initiatives and Training at (202) 366-4900 or online at <http://hazmat.dot.gov/InfectSubstances.pdf>.

IX. Section-by-Section Review

This section-by-section review summarizes the proposed changes believed to be most important, and requests additional comments in some sections.

Part 171

Section 171.8. In § 171.8, we propose to remove the definition for Risk Group.

Part 172

Section 172.101. In the Hazardous Materials Table, we are proposing

several revisions. Most importantly, we are removing the current entry for "Diagnostic Specimens" for consistency with amendments expected to be adopted for 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 propose to revise the entries for "Infectious substances, affecting animals" and "Infectious substances, affecting humans" to delete Special Provision A81 (see discussion below). Further, for consistency with the UN Recommendations, we propose to revise the two entries for toxins to include the phrase "extracted from living sources."

Section 172.102. We are proposing to remove 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 of the changes we propose applicable to shipments of Category B infectious substances. We propose to include quantity limits for air transportation in § 173.199.

Section 172.200. Consistent with requirements in the ICAO Technical Instructions, in § 172.200 we are proposing to clarify that the shipping paper requirements do not apply to Category B infectious substances prepared in accordance with § 173.199 of the HMR. This proposal is consistent with the requirements adopted for the UN Recommendations, which except Category B infectious substances from the shipping paper requirements of Part 172.

Section 172.203. In paragraph (k) of § 172.203, we propose to authorize a shipping paper that accompanies 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 that describes 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, we propose that the technical name of the pathogen must be indicated.

Section 172.301. Consistent with the UN Recommendations, in paragraph (b)

of § 172.301, we propose that no technical names are to be marked on the outer packaging of Division 6.2 materials.

Section 172.800. We propose to require 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. Our August 14, 2002 final rule added Division 6.2 materials to the hazardous materials that may be transported as materials of trade (MOTS). The final rule prohibited Risk Group 4 infectious substances from being transported as MOTS. In this NPRM, we propose to modify § 173.6 to prohibit Category A infectious substances and suspected Category A infectious substances, rather than Risk Group 4 infectious substances, from being transported as MOTS for consistency with the definition and classification criteria for infectious substances adopted for the UN Recommendations. In addition, we propose to modify the packaging requirements for MOTS shipments of Division 6.2 materials. The August 14, 2002 final rule established capacity limitations for MOTS packagings of Division 6.2 materials. In this NPRM, for consistency with international standards, we propose to limit the amount of material each packaging may contain rather than the capacities of the packagings used. Finally, we propose to add a requirement that sharps containers must be securely closed to prevent leaks or punctures. As indicated above, we are concerned that the closures currently being used for sharps containers may not adequately assure that no contents will be released during transportation.

Section 173.24a. We propose to modify paragraph (c) 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 other material 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 proposal 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 proposed 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, in this NPRM, we propose that 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 would 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, would not be permitted to exceed 4 L or 4 kg. Note that this exception applies only to materials in Packing Groups II or III; PG I materials are not authorized. Note also that, 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. We request comments as to whether volumes over 30 mL should be excepted and why, and whether the provision should be expanded to allow Packing Group I materials.

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

(1) We propose to modify the definition for a Division 6.2 material. The proposed definition replaces the Risk Group ranking system with the two-tiered Category A and Category B system adopted by the UN. The proposed 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; UN 3373 for Category B infectious substances; and UN 3291 for Regulated medical waste.

(2) We propose to modify the definition for “biological product” to replace the Risk Group ranking references with references to Category A and Category B infectious substances. We are not proposing to adopt the definition for “biological product” exactly as that term is defined in the UN Recommendations. The new definition

does not differ substantively from the current definition in the HMR; moreover, the current definition in the HMR, as modified in this NPRM, is consistent with the definition used by FDA and other Federal agencies.

(3) We propose to replace the existing definition of “cultures and stocks” with a definition for “cultures” that is 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 proposed in this NPRM 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 proposing a new definition for “patient specimen.” As proposed in this NPRM, “patient specimen” means human or animal materials that are collected directly from humans or animals and that are transported for research, diagnosis, investigational activities, or disease treatment or prevention. Examples include excreta, secretions, blood and its components, tissue and tissue swabs, and body parts.

(5) We propose to modify 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 propose to modify 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 that has 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 proposing to add an exception for dried blood spots and for specimens used to detect fecal occult blood. These are specimens that are routinely 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 that these materials should be transported in a double-envelope system that forms 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 as the inner container placed into a secondary high-quality paper envelope.

In addition, in this NPRM we are proposing to except from regulation under the HMR a human or animal sample transported for routine testing that is not related to diagnosis of an infectious disease and for which there is no reason to suspect that the sample is infectious. Routine screening tests include: (1) Blood or urine tests that 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 a non-infectious disease, such as multiple sclerosis, 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 that are unlikely to cause disease in humans or animals and substances for which there is a low probability that infectious substances are present.

(7) We propose to revise the exceptions in paragraph (c) applicable to the transportation of regulated medical waste. We propose to add a requirement that sharps containers shipped in accordance with this exception must be securely closed to prevent leaks or punctures. We are concerned that the closures currently being used for sharps containers may not adequately assure that no contents will be released during transportation. In addition, we propose to modify

paragraph (c)(2) to revise the current reference to Risk Group 2 or 3 infectious substances to Category B infectious substances.

Section 173.196. We propose to modify the Division 6.2 material packaging requirements in § 173.196 for consistency with the UN Recommendations. Generally, the proposed revisions are editorial and do not change current packaging requirements. We are proposing to add a requirement for outer packaging to be rigid. Note that the packaging requirements in § 173.196 apply to shipments of Category A infectious substances only. In this NPRM, we propose that Category B infectious substances will be transported in accordance with the provisions in § 173.199.

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

We propose to revise § 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(d)(1)(ii)." 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 proposing to revise 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. We propose in paragraph (d)(1)(iv) to not permit untreated concentrated stock cultures of a Category A infectious substance in a wheeled Cart or BOP.

In § 173.197(d)(2)(iii), the reference to the drop test requirement 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."

In § 173.197(e)(3), in the introductory paragraph, we are proposing to revise 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 would make § 173.197(e)(3) consistent with § 173.197(b). Finally, we propose to add a requirement that sharps containers must be securely closed to prevent leaks or punctures. We are concerned that the closures currently being used for sharps containers may not adequately ensure

that no contents will be released during transportation.

Section 173.199. We propose to modify this section for consistency with the UN Recommendations and ICAO Technical Instructions. As proposed in this NPRM, the provisions of § 173.199 will apply to shipments of Category B infectious substances and used health care products. The packaging requirements proposed are substantially the same as the current requirements for shipping diagnostic specimens, except that we are proposing that the outer packaging must be rigid. The completed packaging must be capable of passing a drop test at a height of 1.2 meters. We are proposing 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 propose to require the use of absorbent materials for solids that may become liquid during transportation.

Consistent with amendments adopted for the UN Recommendations, we propose to remove 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 proposing to modify the current limitations on capacity consistent with the amendments adopted in the 2005–2006 ICAO Technical Instructions. For liquids, we propose to increase 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 that is permitted in the outer packaging remains 4 L (1 gallon). For solids, we propose to delete 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). In addition, we propose to require 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 propose to require 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. We are also proposing to require the proper shipping name, UN number, and the name, address, and telephone number of a person knowledgeable about the shipment to 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 able to provide information about how to respond to emergencies or releases involving the package and appropriate first aid and treatment. Finally, we propose to permit 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 would not be 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 that prohibit 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.

Part 175

Section 175.630. We are proposing to add 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.

X. Rulemaking Analysis and Notices

A. Statutory/Legal Authority for This Rulemaking

This NPRM 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 NPRM proposes 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 NPRM proposes to revise 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 NPRM proposes regulations applicable to the transportation of infectious substances in commerce that are consistent with international standards applicable to such transportation. To this end, as discussed in detail earlier in this preamble, the NPRM proposes to harmonize 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 continually 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 without imposing undue burdens on the regulated public. Thus, 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 propose to maintain a number of current exceptions for domestic transportation that should minimize the compliance burden on the regulated community.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This NPRM is a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was reviewed by the Office of Management and Budget. This proposed rule is also considered significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). Benefits resulting from the adoption of the amendments in this NPRM include reduced transportation

costs for shipments of certain infectious substances and enhanced transportation safety and efficiency resulting from consistent domestic and international transportation requirements. The NPRM would 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 NPRM is in the public docket for this rulemaking.

This NPRM proposes to relax 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 proposal, Category B infectious substances could be shipped in non-specification packagings, marked with the appropriate UN number. However, they would be excepted from labeling and shipping documentation requirements. Category B infectious substances would also be excepted from incident reporting requirements, except for shipments by aircraft. Thus, the proposals in this NPRM would reduce transportation costs for many infectious substances and facilitate their rapid and efficient transportation, which is critical to public health.

This NPRM proposes to harmonize 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 efficient transportation of infectious substances across national or international borders. More importantly, harmonized regulations reduce the potential for misunderstanding and confusion and, thus, enhance safety.

C. Executive Order 13132

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (“Federalism”). This proposed rule would preempt State, local, and Indian tribe requirements but does not propose any regulation that has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and

responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

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

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

This proposed rule addresses covered subject items (1), (2), (3), (4), and (5) described above and would preempt State, local, and Indian tribe requirements not meeting the “substantively the same” standard. This proposed 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. PHMSA proposes that the effective date of Federal preemption will be 90 days from publication of a final rule in this matter in the **Federal Register**.

D. Executive Order 13175

This proposed 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 proposals in this NPRM are the more than 441,000 establishments that comprise 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 proposals in this NPRM 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 would incur no increased costs to comply with the provisions of this NPRM; indeed, if adopted, the provisions of this NPRM would 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 that the cost per company will be about \$750/year. In addition, air carriers would incur increased costs associated with new cargo inspection requirements; we estimate that these costs would amount to \$1.34 per package of infectious substances transported. Finally, the NRPM would impose new costs on the regulated industry for shipments of select agents and toxins regulated by USDA; we estimate that 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 proposals in this NPRM 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 NPRM 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 that ship infectious substances could expect to experience an average cost savings of \$77 per shipment 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 NPRM would result in enhanced security for the transportation of select agents. Finally, the NPRM would remove 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, PHMSA certifies that while this proposed rule will impact a significant number of small entities it will not have a significant economic impact on a substantial number of small entities.

This proposed 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 that potential impacts of draft rules on small entities are properly considered.

F. Unfunded Mandates Reform Act of 1995

This proposed rule would not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It would not, if adopted, 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 proposed 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 proposed rule. PHMSA proposes 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

Anyone is able to search the electronic form for all comments received into any of our dockets 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 propose to amend 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 entries “Diagnostic specimen”; “Toxins, from living sources, liquid, n.o.s.”; and “Toxins, from living sources, solid, n.o.s.” are removed.

b. The entries “Biological substance, Category B”; “Toxins, extracted from living sources, liquid, n.o.s.”; and “Toxins, extracted from living sources, solid, n.o.s.” are 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 UN 2914 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 [six months after effective date of final rule], 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

9a. 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, that is 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 all Division 6.2 materials, 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. Such materials are not subject to the requirements of this subchapter.

* * * * *

12. In § 173.134, paragraph (a) introductory text and, (a)(1) through (a)(5) are revised; paragraph (a)(6) is removed; paragraphs (a)(7), (a)(8), and (a)(9) are redesignated as 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 that is 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 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 that is 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 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 manufactured and distributed in accordance with one of the following provisions: 9 CFR part 102 (Licenses for Biological Products); 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR part 104 (Permits for Biological Products); 21 CFR part 312 (Investigational New Drug Application); 21 CFR part 314 (Applications for FDA Approval to Market a New Drug); 21 CFR parts 600 to 680 (Biologics); or 21 CFR part 812 (Investigational Device Exemptions). 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 materials that are collected directly from humans or animals and that are 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 that contains microorganisms that are non-pathogenic to humans or animals.

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

(5) A material that has 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, that is 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)(4) 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 that is 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 that the sample is infectious.

(12) 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.

(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 concentrated stock 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.

* * * * *

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) *Category A 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)(1)(ii) 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.

* * * * *

(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. 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) are revised, paragraphs (d) and (e) are redesignated (e) and (f), respectively, new paragraph (d) is added, and redesignated paragraphs (e) introductory text and (f) are revised, to read as follows:

§ 173.199 Category B infectious substances and used health care products.

(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

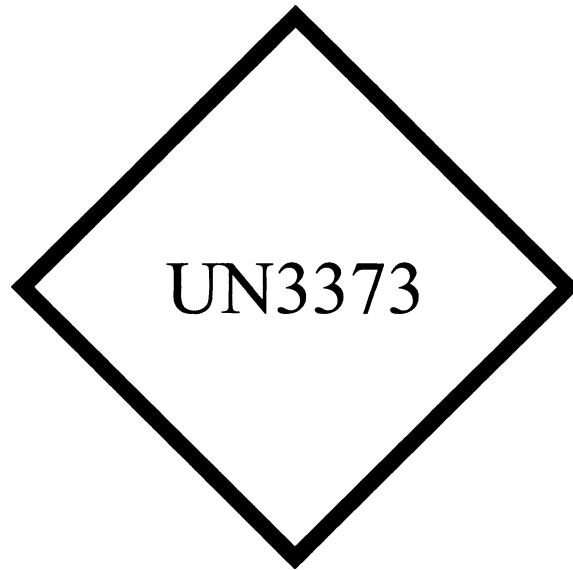
secondary packaging, and a rigid outer packaging.

(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 test in § 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Following the drop test, 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, address, 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 or overpack 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 or overpack 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 materials 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 there is any doubt as to whether 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.

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

* * * * *

(f) *Training*. Each person who offers or transports a Category B infectious substance or used health care product 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 or overpack 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 or overpack 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 10, 2005, under the authority delegated in 49 CFR part 106.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

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