

relevant communicable disease testing; or

(ii) An algorithm designed to ensure that plasma dilution sufficient to affect test results has not occurred is utilized to evaluate the volumes administered in the 48 hours prior to collecting the specimen from the donor;

(3) A donor who is 12 years of age or younger and has received any transfusion of blood, colloids, and/or crystalloids prior to the recovery of the cells or tissue, unless:

(i) A specimen taken from the donor before the transfusion or infusion is available for relevant communicable disease testing; or

(ii) An algorithm designed to ensure that plasma dilution sufficient to affect test results has not occurred is utilized to evaluate the volumes administered in the 48 hours prior to collecting the specimen from the donor.

§ 1271.85 Donor testing; specific requirements.

(a) To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, a specimen from a donor of viable or nonviable cells or tissue for a human cellular or tissue-based product shall be tested for evidence of infection due to relevant communicable disease agents including, at a minimum, the communicable disease agents listed as follows.

(1) Human immunodeficiency virus, type 1;

(2) Human immunodeficiency virus, type 2;

(3) Hepatitis B virus;

(4) Hepatitis C virus; and

(5) *Treponema pallidum*.

(b) To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, a specimen from a donor of viable, leukocyte-rich cells or tissue shall be tested for evidence of infection due to the relevant cell-associated communicable disease agents including, at a minimum, the communicable disease agents listed as follows, in addition to the relevant communicable disease agents for which testing is required under paragraph (a) of this section.

(1) Human T-lymphotropic virus, type I;

(2) Human T-lymphotropic virus, type II; and

(3) Cytomegalovirus.

(c) To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, a

specimen from a donor of reproductive cells or tissue shall be tested for evidence of infection due to relevant genitourinary disease agents. Testing shall include, at a minimum, the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section, in addition to the relevant communicable disease agents for which testing is required under paragraphs (a) and (b) of this section. However, if the reproductive cells or tissue are procured by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract, then tests for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section are not required. Minimum testing for genitourinary disease agents include:

(1) *Chlamydia trachomatis*; and

(2) *Neisseria gonorrhea*.

(d) Except as provided under § 1271.90, at least 6 months after the date of donation of reproductive cells or tissue that can be reliably stored, a new specimen shall be taken from the donor and retested for evidence of infection due to the relevant communicable disease agents for which testing is required under paragraphs (a), (b), and (c) of this section.

(e) For donors of dura mater, an assessment designed to detect evidence of transmissible spongiform encephalopathy shall be performed.

§ 1271.90 Exceptions from the requirement of donor suitability determination; labeling requirements.

(a) For the following human cellular and tissue-based products, a determination of donor suitability under § 1271.50 is not required, and donor screening under § 1271.75, and testing under §§ 1271.80 and 1271.85 are recommended but not required:

(1) Banked cells and tissues for autologous use;

(2) Reproductive cells or tissue donated by a sexually-intimate partner of the recipient for reproductive use.

(b) If all screening and testing applicable to a comparable human cellular or tissue-based product under §§ 1271.75, 1271.80, and 1271.85 are not performed on the donor of a human cellular or tissue-based product listed in paragraph (a) of this section, the product shall be labeled "NOT EVALUATED FOR INFECTIOUS SUBSTANCES." If any screening or testing is performed on a donor of a human cellular or tissue-based product listed in paragraph (a) of this section, and the results indicate the presence of relevant communicable disease agents and/or risk factors for or clinical evidence of relevant

communicable disease agents or diseases, the product shall be labeled with the Biohazard legend shown in § 1271.3(i).

(c) Banked cells and tissues for autologous use shall be labeled "FOR AUTOLOGOUS USE ONLY."

Dated: February 19, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Dated: August 29, 1999.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 100, 110, and 165

[CGD05-99-068]

OPSAIL 2000, Port of Hampton Roads, VA

AGENCY: Coast Guard, DOT.

ACTION: Advanced notice of proposed rulemaking; request for comments.

SUMMARY: The Coast Guard requests public comment on the temporary establishment of several exclusion areas and anchorage grounds before, during, and after OPSAIL 2000 in the Port of Hampton Roads, Virginia, from June 14 through June 20, 2000. The Coast Guard anticipates rulemaking establishing Special Local Regulations to control vessel traffic within the Port of Hampton Roads 2 days prior to the event on June 14 and 15, 2000; establishing several exclusion areas; establishing new and/or assigning currently designated Anchorage Grounds for participating/spectator vessels; and establishing temporary safety zones for fireworks displays.

DATES: Comments must be received on or before November 15, 1999.

ADDRESSES: Comments may be mailed to the Port Operations Department (CGD05-99-068), Coast Guard Marine Safety Office Hampton Roads, 200 Granby Street, Norfolk, Virginia 23510, or delivered to the 7th floor at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The Port Operations Department of Marine Safety Office Hampton Roads maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at the Coast Guard Marine Safety Office

Hampton Roads, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander S. Moody or Lieutenant L. Greene, Port Operations Department, Coast Guard Marine Safety Office Hampton Roads (757) 441-3294, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in the early stages of this rulemaking by submitting written data, views, or arguments. Please explain your reasons for each comment so that we can carefully weigh the consequences and impacts of any future requirements we may propose. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD05-99-068) and the specific section of this document to which each comment applies. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes. The Coast Guard will consider all comments received during the comment period.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Port Operations Department at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Opsail 2000 is sponsoring the OPSAIL 2000 Parade of Tall Ships, as well as a fireworks display. These events are scheduled to take place on June 16 and 17, 2000 respectively, in the Port of Hampton Roads, on the waters of Chesapeake Bay and the Elizabeth River. The Coast Guard expects a minimum of 10,000 spectator craft for this event. The anticipated rulemaking will provide specific guidance on temporary anchorage regulations, vessel movement controls, safety and security zones that will be in effect at various times in those waters during the period June 14–20, 2000. The Coast Guard may seek to establish additional regulated areas, Anchorage Grounds, and safety or

security zones once confirmation of the exact number of vessels and dignitaries that will be participating in OPSAIL 2000 becomes available.

Schedule of Events

At the current time, marine related events will include the following:

1. June 15 and 16, 2000: The arrival of more than 200 Tall Ships and character vessels at Lynnhaven Anchorage.

2. June 16, 2000: Parade of approximately 200 Tall Ships and character vessels from Cape Henry to Town Point Park, Downtown Norfolk.

3. June 17, 2000: Fireworks display scheduled to take place adjacent to the Norfolk and Portsmouth Seawalls.

4. June 20, 2000: Scheduled departure for the majority of the vessels.

Discussion

The Coast Guard estimates there will be over 10,000 spectator craft and commercial vessels (passenger vessels and charter boats) in the area during June 16 through 20, 2000. The safety of parade participants and spectators will require that spectator craft be kept at a safe distance from the parade route. The Coast Guard intends to establish multiple limited access areas for the vessel parade, and to temporarily modify existing anchorage areas within the port area to provide for maximum spectator viewing areas and traffic patterns for deep draft and barge traffic.

The most severe traffic restrictions will be in place during the Parade of Sail, which will begin the morning of June 16 and end that evening. These restrictions will affect all vessels. The only other restriction anticipated for commercial deep draft and barge traffic will be during the fireworks display on Saturday night, June 17. The Coast Guard anticipates having vessels available on request to escort deep draft and barge traffic through congested areas of Town Point Reach during all other periods of June 16–20, 2000.

Regulatory Evaluation

At this early stage in what is still just a potential rulemaking, the Coast Guard has not determined whether any future rulemaking may be considered a significant regulatory action under section 3(f) of Executive Order 12866 or the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of any future rulemaking to be minimal. Although the Coast Guard anticipates restricting traffic from transiting a portion of the Elizabeth River, Newport News channel

and some anchorages during the vessel parade, the effect of any future rulemaking will be minimized because of the limited duration of the event and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, facsimile, the internet, marine information broadcasts, Hampton Roads Maritime Association meetings, and Hampton Roads area newspapers, so mariners can adjust their plans accordingly. The Coast Guard anticipates that the majority of the maritime industrial activity in the Port of Hampton Roads will continue, relatively unaffected by any future rulemaking.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether any potential rulemaking, if it led to an actual rule, would have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard does not anticipate that its potential rulemaking will have anything but a minimal impact upon small entities, but expects that comments received on this advance notice will help it determine the number of potentially affected small entities and in weighing the impacts of various regulatory alternatives for the purpose of drafting any rules.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Act of 1996 [Pub. L. 104–121], the Coast Guard wants to assist small entities in understanding this advance notice so that they can better evaluate the potential effects of any future rulemaking on them and participate in the rulemaking. If you believe that your small business, organization, or agency may be affected by any future rulemaking, and if you have questions concerning this notice, please consult the Coast Guard point of contact designated in **FOR FURTHER INFORMATION CONTACT**. The Coast Guard is particularly interested in how any future rulemaking may affect small entities. If you are a small entity and believe that you may be affected by such a rulemaking, please tell how, and what flexibility or compliance alternatives the Coast Guard should consider to minimize the burden on small entities while promoting port safety.

Collection of Information

The Coast Guard anticipates that any future rulemaking will not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this advanced notice under the principles and criteria contained in Executive Order 12612. From the information available at this time, the Coast Guard cannot determine whether this potential rulemaking would have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), the Coast Guard must consider whether this potential rulemaking will result in an annual expenditure by state, local, and tribal governments, in the aggregate of \$100 million (adjusted annually for inflation). If so, the Act requires that a reasonable number of regulatory alternatives be considered, and that from those alternatives, the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule be selected. The Coast Guard does not anticipate that any future rulemaking will result in such expenditures, but welcomes comments addressing the issue from interested parties.

Environment

The Coast Guard anticipates that any potential rulemaking would be categorically excluded from further environmental documentation in accordance with Commandant Instruction M16475.1C. Any such rulemaking would be designed to minimize the likelihood of maritime disasters with their attendant environmental consequences and to enhance the safety of participants, spectators, and other maritime traffic. Therefore, any potential rulemaking should have no environmental impact. The Coast Guard invites comments addressing possible effects that any such rulemaking may have on the human environment or addressing possible inconsistencies with any Federal, State, or local law or administrative determinations relating to the environment. It will reach a final determination regarding the need for an

environmental assessment after receipt of relevant comments.

J.E. Schrinner,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 99-25448 Filed 9-29-99; 8:45 am]

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POSTAL RATE COMMISSION

39 CFR Part 3001

[Docket No. RM98-2; Order No. 1263]

Revisions To Library Reference Rule; Further Changes

AGENCY: Postal Rate Commission.

ACTION: Supplementary notice of proposed rule.

SUMMARY: This document addresses comments on a previous proposal to revise rules on the use of library references. It also presents another set of revisions for comment. The revisions are intended to improve administrative aspects of the library reference practice.

DATES: File comments by October 20, 1999.

ADDRESSES: Send comments on this proposal to Margaret P. Crenshaw, Secretary of the Commission, Postal Rate Commission, 1333 H Street, NW., Suite 300, Washington, DC 20268-0001.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202-789-6820.

SUPPLEMENTARY INFORMATION:

Regulatory History

On September 8, 1998, the Commission published order no. 1219 in the **Federal Register** (63 FR 47456) setting forth its initial proposal to revise rule 31(b) (39 CFR 3001.31(b)). The Commission received eight sets of comments on the proposal. In order no. 1223 (issued December 24, 1999), the Commission proposed further revisions. These were published in the **Federal Register** on December 24, 1998 (63 FR 71251). The Commission received three sets of comments on the amended version of the rule. Comments on both orders are available for public inspection in the Commission's docket section. They also can be accessed electronically at www.prc.gov. The Commission issued this order (no. 1263) proposing further revisions on September 23, 1999. It directed interested parties are invited to submit comments following publication of this proposal in the **Federal Register** (see Dates for the deadline) and directed the Secretary to cause this order to be published in the **Federal Register**, in

accordance with all applicable regulations of the Office of the Federal Register.

Introduction

This is the third order the Commission has issued in a rulemaking revising rule 31(b) provisions on the practice of filing library references. It briefly describes previous proposals, addresses various comments, and presents further proposed revisions. The proposed changes reflect the same focus on limited administrative improvements as the earlier proposals, but place greater emphasis on the role of the notice in providing relevant information. Inclusion of a detailed preface or summary, which had been proposed as a mandatory requirement, is made optional. New provisions, based on a Postal Service analysis, identify six categories of library references. The proposal also clarifies when library references may be filed and when special requests for service can be made. The rule has been reorganized and renumbered to reflect these changes (consistent with Office of the Federal Register style.) Minor editorial revisions also have been made.

I. Summary of Initial Proposal (Order No. 1219)

The initial set of provisions issued in this rulemaking listed the circumstances when material could be filed as a library reference. The list reflected the practice that had grown up around the existing rule. It included the following independent considerations: When physical characteristics (such as bulk or volume) make service of the material unduly burdensome; when the material is of limited interest to the entire service list; when the material qualifies as a secondary source; when reference to the material is made easier or otherwise facilitated; or when otherwise justified by circumstances, as determined by the Commission or presiding officer.

The initial proposal also required those who file library references ("filers") to provide detailed information and related disclosures about the material in both an accompanying motion and in a preface or summary contained in the library reference. This represented a change in practice, as the long-standing rule has required only a notice with minimal information. The proposal also required submission of an electronic version of material.