

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 16 and 1270**

[Docket No. 93N-0453]

**Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives; Notice of Public Workshop**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled "Human Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives." The purpose of this workshop is to provide an opportunity for continued discussion of the regulation of human tissue for transplantation as outlined by FDA in an interim rule that published in the **Federal Register** of December 14, 1993. The workshop will include discussions of other related issues, including regulating reproductive tissue.

**DATES:** The public workshop will be held on Tuesday and Wednesday, June 20 and 21, 1995, 8:30 a.m. to 5:30 p.m. Preregistration is requested by Friday, June 9, 1995.

**ADDRESSES:** The public workshop will be held at the National Institutes of Health, Bldg. 45, Natcher Auditorium, 9000 Rockville Pike, Bethesda, MD. There is no registration fee.

**FOR FURTHER INFORMATION CONTACT:**

Regarding information on registration: Julie Furman, KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD 20910, 301-495-1591, or FAX 301-495-9410.

Regarding information on this document: Marty A. Wells, Center for Biologics Evaluation and Research (HFM-305), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0967.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA published an interim rule on human tissue intended for transplantation. This interim rule requires certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of acquired immune deficiency syndrome (AIDS) and hepatitis through human tissue used in transplantation. The regulations in the

interim rule became effective upon publication.

The objectives of the public workshop are to: (1) Promote an understanding of related public health issues based on scientific knowledge; (2) provide an opportunity for discussion of current donor screening and testing practices for human tissue for transplantation and human reproductive tissue; (3) identify the practices and procedures of the procurer, processor, distributor, and user of human tissue for transplantation and human reproductive tissue and their interactions; and (4) examine the existing state and industry approaches to the regulation of human tissue for transplantation and human reproductive tissue.

The workshop will consist of plenary and breakout sessions that will include the following topics: (1) Donor screening; (2) infectious disease testing and inactivation methods; (3) voluntary standards; (4) assessment of industry practices related to tracking; (5) interactions with organ procurement organizations and procurement coordination practices; and (6) state regulatory approaches and industry practices.

Dated: May 19, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-12763 Filed 5-19-95; 3:29 pm]

BILLING CODE 4160-01-F

**DEPARTMENT OF TRANSPORTATION****Coast Guard****33 CFR Part 165**

[CGD13-95-017]

**Safety Zone Regulations; Portland Rose Festival Fireworks Display, Willamette River, Portland, OR**

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone for the Portland Rose Festival Fireworks Display which is scheduled to be held in Portland, Oregon, on June 2, 1995. The safety zone will be located on the Willamette River between the Morrison and Hawthorne Bridges from river mile 12.8 to river mile 13.1. This safety zone is needed to protect persons, facilities, and vessels from safety hazards associated with the fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATE:** This regulation becomes effective on June 2, 1995, at 8:45 p.m. (PDT) and terminates on June 2, 1995, at 11:10 p.m. (PDT), unless

sooner terminated by the Captain of the Port. If inclement weather causes the fireworks display to be postponed, this regulation will be effective on June 4, 1995, from 8:45 p.m. (PDT) to 11:10 p.m. (PDT), unless sooner terminated by the Captain of the Port.

**FOR FURTHER INFORMATION CONTACT:**

LTJG C.A. Roskam, c/o Captain of the Port Portland, 6767 N. Basin Ave, Portland, Oregon 97217-3992, (503) 240-9338.

**SUPPLEMENTARY INFORMATION:****Regulatory History**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective less than 30 days after **Federal Register** publication. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is necessary to ensure the safety of structures and vessels operating in the area of the fireworks display. Due to the complex planning and coordination involved, the event sponsor, the Portland Rose Festival Association, was unable to provide the Coast Guard with notice of the final details until 30 days prior to the date of the event. Therefore, sufficient time was not available to publish the proposed rule in advance of the event or to provide a delayed effective date. Following normal rulemaking procedures in this case would be impracticable.

**Drafting Information**

The principal persons involved in drafting this document are LTJG C.A. Roskam, Project Officer for the Captain of the Port of Portland, OR, and LCDR J.C. Odell, Project Counsel, Thirteenth Coast Guard District Legal Office.

**Background and Purpose**

The event requiring this regulation is a fireworks display sponsored by the Portland Rose Festival Association, as part of the Portland Rose Festival in the Portland, Oregon, area. The fireworks display is scheduled to begin on June 2, 1995, at 9:45 p.m. (PDT). If the fireworks display cannot be held on June 2, 1995, because of inclement weather, it will be rescheduled for June 4, 1995, at 9:45 p.m. (PDT).

During the fireworks display, spectator vessels may attempt to approach the fireworks launching barge at close range. If allowed to do so, these vessels and the persons onboard them may be exposed to potential damage, fire, and personal injury due to sparks, falling debris, and unexploded fireworks.

In order to protect the safety of life and property on the navigable waters during this event, the Coast Guard is establishing a safety zone around the fireworks launching barge on the waters of the Willamette River from river mile 12.8 to river mile 13.1 between the Morrison and Hawthorne Bridges. Entry into this zone will be prohibited unless authorized by the captain of the Port. This safety zone will be enforced by representatives of the Captain of the Port Portland. The Captain of the Port may be assisted by other federal agencies.

#### Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under 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 this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This expectation is based on the fact that the entry into the safety zone will only be restricted for less than 3 hours on the day of the event. The entities most likely to be affected by this action are commercial tug and barge operators on the Willamette River. Most of these entities are aware of the fireworks display and the safety zone, and they can schedule their transits accordingly. If safe to do so, the representative of the Captain of the Port assigned to enforce this safety zone may authorize commercial vessels to pass through the safety zone on a case-by-case basis.

#### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this final rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

For the reasons outlined in the Regulatory Evaluation above, the Coast Guard expects the impact of this final rule to be minimal on all entities. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule

will not have a significant economic impact on a substantial number of small entities.

#### Collection of Information

This final rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

#### Federalism

The Coast Guard has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Environmental Assessment

The Coast Guard has considered the environmental impact of this final rule and has concluded that, under section 2.B.2.c. of Commandant Instruction M16475.1B, it is categorically excluded from further environmental documentation. A Categorical Exclusion Determination has been prepared and placed in the rulemaking docket.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

#### Final Regulation

For the reasons set out in the preamble, the Coast Guard amends part 165 of title 33, Code of Federal Regulations, as follows:

#### PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; 49 CFR 1.46.

2. A temporary § 165.T13015 is added to read as follows:

#### § 165.T13015 Safety Zone; Willamette River, Portland, OR.

(a) *Location.* The following area is a safety zone: All waters on the Willamette River between the Morrison and Hawthorne Bridges from river mile 12.8 to river mile 13.1, Portland, Oregon.

(b) The designated representative of the Captain of The Port is any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Portland, to act on his behalf. The following officers have or will be designated by the Captain of the Port: The Coast Guard Patrol Commander, the senior boarding officer

on each vessel enforcing the safety zone, and the Duty Officer at Coast Guard Group Portland, Oregon.

(c) *Regulations:* (1) In accordance with the general regulations in § 165.23 of this part, entry into this safety zone is prohibited unless authorized by the Captain of the Port or his designated representatives.

(2) A succession of sharp, short signals by whistle, siren, or horn from vessels patrolling the area under the direction of the Patrol Commander shall serve as a signal to stop. Vessels or persons signalled shall stop and comply with the orders of the patrol vessels; failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(d) *Effective Dates:* This section becomes effective on June 2, 1995, at 8:45 p.m. (PDT) and terminate on June 2, 1995, at 11:10 p.m. (PDT), unless sooner terminated by the Captain of the Port. If inclement weather causes the fireworks display to be postponed, the regulation will be effective on June 4, 1995, from 8:45 p.m. (PDT) to 11:10 p.m. (PDT), unless sooner terminated by the Captain of the Port.

Dated: May 9, 1995.

#### C.E. Bills,

*Captain, U.S. Coast Guard, Captain of the Port.*

[FR Doc. 95-12737 Filed 5-23-95; 8:45 am]

BILLING CODE 4910-14-M

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900-AF03

#### Line of Duty

**AGENCY:** Department of Veterans Affairs.  
**ACTION:** Final rule.

**SUMMARY:** This document amends Department of Veterans Affairs (VA) adjudication regulations concerning service connection for disabilities incurred or aggravated in line of duty. This amendment is necessary to implement legislation which precludes the establishment of service connection for any condition that results from the abuse of alcohol or drugs by the person on whose service benefits are claimed.  
**EFFECTIVE DATE:** November 1, 1990.

**FOR FURTHER INFORMATION CONTACT:** Lorna Weston, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273-7210.