

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

59. Section 884.4530 is amended by revising paragraph (b)(2) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, intrauterine device (IUD) remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a gynecological biopsy forceps that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

60. Section 884.6100 is amended by revising paragraph (b) to read as follows:

§ 884.6100 Assisted reproduction needles.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 886—OPHTHALMIC DEVICES

61. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

62. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. If the device is an ophthalmic knife that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

63. Section 886.4370 is amended by revising paragraph (b) to read as follows:

§ 886.4370 Keratome.

* * * * *

(b) *Classification.* Class I (general controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

64. Section 886.4670 is amended by revising paragraph (b) to read as follows:

§ 886.4670 Phacofragmentation system.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a phacoemulsification needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 892—RADIOLOGY DEVICES

65. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

66. Section 892.5730 is amended by revising paragraph (b) to read as follows:

§ 892.5730 Radionuclide brachytherapy source.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an isotope needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

Dated: September 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-8165 Filed 9-22-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 06-036]

RIN 1625-AA00

Safety Zone; Red Bull Air Show Practice, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a safety zone to be used to keep spectator vessels out of the path and away from the area directly below participating aircraft during the fleet week air show practice in order to ensure the safety of event participants and spectators.

DATES: Comments and related material must reach the Coast Guard on or before October 10, 2006.

ADDRESSES: You may mail comments and related material to the Waterways Safety Branch, U.S. Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California 94130. The Waterways Safety Branch maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the Waterways Safety Branch between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Erin Bastick, U.S. Coast Guard Sector San Francisco, at (415) 556-2950 or Sector San Francisco 24 hour Command Center at (415) 399-3547.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (COTP San Francisco Bay 06-036), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may

change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the Waterways Safety Branch at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a separate notice in the **Federal Register**.

Background and Purpose

On October 1, 1993, the Coast Guard published a final rule (58 FR 51242) modifying the regulations in 33 CFR 100.1105, that establish regulated areas to ensure the safe execution of the San Francisco Bay Navy Fleet Week Parade of Ships and Air Show Demonstration. The U.S. Navy and City of San Francisco are sponsoring the Annual Fleet Week Parade of Navy Ships and Air Show Demonstration to be held October 5 thru October 8, 2006. The Red Bull practice will be held on October 4, 2006 from 10 a.m. through 2 p.m., in order to allow sufficient time to practice prior to the scheduled Fleet Week Air Show Demonstration.

Due to the safety concerns associated with the air show practice demonstration, this safety zone is necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area.

Discussion of Proposed Rule

The safety zone will include all navigable waters, from the surface to the seafloor, encompassed by connecting the following points to form an approximate square security zone, beginning at 37°48'29.50" N, 122°26'34.08" W, thence 37° 48'29.32" N, 122°26'28.65" W, thence 37°48'24.95" N, 122°26'25.25" W, thence 37°48'31.24" N, 122°25'38.66" W, thence 37°48'37.96" N, 122°25'33.80" W, thence 37°48'40.70" N, 122°25'24.74" W, thence 37°48'51.90" N, 122°25'24.79" W, lastly to 37°48'49.14" N, 122°26'34.08" W.

No person or vessel may enter or remain within the safety zone unless authorized by the Captain of the Port (COTP), Sector San Francisco, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this safety zone.

Because this safety zone will be in effect for a limited period, it should not result in a significant disruption to maritime traffic. Additionally, the maritime community will be provided

advance notification of these events via public broadcast notice to mariners.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary.

Although this safety zone restricts access to a portion of the navigable waters, the effect of this zone will not be significant because: (i) The zone encompasses only a small portion of the waterway; (ii) vessels are able to pass safely around the zone; and (iii) the practice is a short duration in time, lasting only 4 hours.

The size of the zone is the minimum necessary to provide adequate protection for personnel or vessels during live fire training. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing and commercial fishing vessels.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises 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 certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities. Although this safety zone prevents traffic from transiting a portion of San Francisco Bay during the air show practice, the effect of this zone will not be significant because small vessels will be able to transit around the regulated area and the duration of the safety zone is limited to four hours in length. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing.

Small entities and the maritime public will also be advised of this safety zone via public broadcast notice to mariners. In addition, vessels will be able to pass through the zone on a case-by-case basis. Therefore, the economic

impact of this waterway closure is not expected to be significant.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the Waterways Safety Branch at the address under **ADDRESSES**. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental

Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or

operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.ID and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T11–144 to read as follows:

§ 165.T11–144 Safety Zone; Red Bull Air Show Practice, San Francisco Bay, CA.

(a) *Location.* The safety zone will include all navigable waters, from the surface to the seafloor, encompassed by connecting the following points to form an approximate square security zone, beginning at 37°48'29.50" N, 122°26'34.08" W, thence 37°48'29.32" N, 122°26'28.65" W, thence 37°48'24.95" N, 122°26'25.25" W, thence 37°48'31.24" N, 122°25'38.66" W, thence 37°48'37.96" N, 122°25'33.80" W, thence 37°48'40.70" N,

122°25'24.74" W, thence 37°48'51.90" N, 122°25'24.79" W, lastly to 37°48'49.14" N, 122°26'34.08" W.

(b) *Definitions.* As used in this section: (1) *Designated representative* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Captain of the Port (COTP), Coast Guard Sector San Francisco, or a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the safety zone.

(2) [Reserved]

(c) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or his designated representative.

(2) Vessel operators desiring to enter or operate within the safety zone may contact the COTP or his representative at telephone number 415–399–3547 or on VHF–FM channel 16 (156.8 MHz). Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or his designated representative.

(d) *Enforcement and suspension of enforcement of certain safety zones.* The COTP will provide notice of the enforcement of the safety zones listed in paragraph (a) of this section and notice of suspension of enforcement by the means appropriate to affect the widest publicity, including broadcast notice to mariners and publication in the local notice to mariners.

(e) *Effective period.* This section is effective October 4, 2006 from 10 a.m. through 2 p.m.

Dated: September 8, 2006.

W. J. Uberti,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco, California.

[FR Doc. 06–8134 Filed 9–22–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 175, 177, 178, and 180

[Docket No. PHMSA–05–21812 (HM–218D)]

RIN 2137–AE10

Hazardous Materials; Miscellaneous Amendments

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