

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.

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(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.

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(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.

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(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.

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(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.

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(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.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 06-022]

RIN 1625-AA00

Safety Zone; BART Transbay Tube Seismic Upgrade, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a moving temporary safety zone in the navigable waters of San Francisco Bay, California during vibro penetration testing for a seismic upgrade of the Bay Area Rapid Transit (BART) Transbay tube. The testing will require placement of a barge at test sites along the BART Transbay tube. The safety zone will surround the barge and move with the barge as it conducts the tests at seven sites along the BART Transbay tube. This safety zone is necessary to protect persons and vessels from hazards, injury, and damage associated

with the vibro penetration testing. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from September 25, 2006 through December 31, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket COTP San Francisco Bay 06-022 and are available for inspection or copying at the Waterways Safety Branch of Sector San Francisco, Yerba Buena Island, Bldg. 278, San Francisco, California, 94130, 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:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The dates for the vibro penetration testing along the Transbay tube were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the testing would commence before the rulemaking process could be completed. Any delay in implementing this rule is contrary to the public interest since immediate action is necessary in order to protect the maritime public from the hazards associated with the vibro penetration testing.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The dates for the vibro penetration testing along the Transbay tube were not finalized and presented to the Coast Guard in time to publish this rule 30 days prior to its effective date. As such, the testing would commence before the rulemaking process could be completed. Delay in the effective date of this rule would expose the mariners and waterways users to undue hazards associated with the vibro penetration testing.

Background and Purpose

Bay Area Rapid Transit has contracted Hayward Baker, Soletanche, Traylor, A Joint Venture, to conduct BART marine demonstration tests in support of their earthquake safety efforts. They will be

conducting vibro penetration tests for future seismic upgrade of the BART Transbay tube. The scope of work involves four primary activities carried out on the water. These activities include vibro penetration tests, vibro ground improvement, drilling, sampling and sonic borings.

The Joint Venture's work will involve outfitting the barge DOGBONE with a crane and vibratory densification equipment and locating it over the tube alignment to perform the ground improvement within the test areas. At times there will be an additional barge lashed to the barge DOGBONE for material handling. Approximately ten 5-foot tall tripods with acoustic transponders will be deployed on the bay bottom to determine specific test locations along the BART Transbay. At each specified location the crane suspended vibrator will be lowered into the bay floor and then proceed to densify the granular backfill placed around the tubes shortly after they were originally placed into position.

Discussion of Rule

This safety zone will encompass the navigable waters from the surface to the sea floor, located in the San Francisco Bay, encompassing a circular safety zone with a 750-foot radius extending from the Crane Barge DOGBONE. The Barge DOGBONE will transit and conduct testing along the BART Transbay tube between two points: 37°47'50.97" N Latitude by 122°23'17.01" W Longitude at the western extreme and 37°48'25.65" N Latitude by 122°21'03.59" W Longitude on the eastern extreme. This area between the two points will be used to maneuver and anchor the Barge DOGBONE as it conducts the vibro penetration tests from September 25, 2006 through December 31, 2006. The BART Project manager coordinated the test locations with the local Bar Pilots and the Vessel Traffic Service to ensure the testing would result in minimum impact to vessel traffic. This moving safety zone around the Barge DOGBONE is necessary to protect persons and vessels from hazards, injury, and damage associated with the vibro penetration testing.

U.S. Coast Guard personnel will enforce this safety zone. Other Federal, State, or local agencies may assist the Coast Guard, including the Coast Guard Auxiliary. Section 165.53 of Title 33, Code of Federal Regulations, prohibits any unauthorized person or vessel from entering or remaining in a safety zone. Vessels or persons violating this section may be subject to both criminal and civil penalties.

Regulatory Evaluation

This 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.

Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users have been contacted to ensure the closure will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities. Not only is the safety zone small in size, but there will be ample space to navigate around the safety zone as well.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in a portion of the San Francisco Bay from September 25, 2006 through December 31, 2006.

We expect this rule may affect owners and operators of vessels, some of which may be small entities, intending to fish, sightsee, transit, or anchor in the waters affected by this safety zone. This safety zone will not have a significant economic impact on a substantial number of small entities for several reasons: small vessel traffic will be able to pass safely around the area and vessels engaged in recreational activities, sightseeing and commercial fishing have ample space outside of the safety zone to engage in these activities. 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.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls 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 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 rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect 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 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 rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this 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 concluded 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, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Paragraph (34)(g) is applicable because this rule establishes a safety zone.

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 amends 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.T11–146, to read as follows:

§ 165.T11–110 Safety Zone; San Francisco Bay, California.

(a) *Location.* This safety zone will encompass the navigable waters from the surface to the sea floor, in the San Francisco Bay, and its limits will encompass a circular safety zone with a radius of 750-feet extending from and around the Crane Barge DOGBONE. This safety zone will move and continue to extend 750-feet from the Barge DOGBONE while it operates along the charted BART Transbay tube between the following two points: 37°47'50.97" N Latitude, by 122°23'17.01"W Longitude at the western extreme, and 37°48'25.65"N Latitude by

122°21'03.59"W Longitude at the eastern extreme.

(b) *Effective Dates.* This rule is effective from September 25, 2006 through December 31, 2006. If the need for the safety zone ends prior to the scheduled termination time, the Captain of the Port (COTP) will cease enforcement of the safety zone.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone by all vessels and persons is prohibited, unless specifically authorized by the COTP San Francisco, or his designated representative.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard COTP or his designated representative. The COTP's designated representative can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, State, and Federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

The U.S. Coast Guard may be assisted in the patrol and enforcement of these two safety zones by local law enforcement as necessary.

Dated: September 8, 2006.

W.J. Uberti,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Western Alaska 06–003]

RIN 1625–AA00

Safety Zone; Gulf of Alaska, Narrow Cape, Kodiak Island, AK

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the Gulf of Alaska, encompassing the navigable waters in the vicinity of Narrow Cape and Ugak Island. The zone is needed to protect persons and vessels operating in the vicinity of the safety zone during a rocket launch from the Alaska Aerospace Development Corporation, Narrow Cape, Kodiak