

and needle, device placement tool, connector assembly tool, incision closing tool, corporeal dilator, tubing passer, measurement tool or tape, tubing plug, blunt needle, and hemostat shod tubing.

(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 § 876.9.

■ 4. Add § 876.4630 to subpart E to read as follows:

§ 876.4630 Ureteral stent accessories.

(a) *Identification*. Ureteral stent accessories aid in the insertion of the ureteral stent that is placed into the ureter to provide ureteral rigidity and allow the passage of urine. This generic type of device includes the stent positioner, wire guide, and pigtail straightener.

(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 § 876.9.

■ 5. Add § 876.5012 to subpart F to read as follows:

§ 876.5012 Biliary stent, drain, and dilator accessories.

(a) *Identification*. Biliary stent, drain, and dilator accessories are manual devices that aid in the introduction and connection of biliary stents, drains, or dilators. This generic type of device includes the guiding catheter, pushing catheter, pigtail straightener, flap protector, nasal transfer tube, and drainage connecting tube.

(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 § 876.9.

■ 6. Add § 876.5100 to subpart F to read as follows:

§ 876.5100 Suprapubic catheter accessories.

(a) *Identification*. Suprapubic catheter accessories are manual devices that are used to facilitate the placement of a suprapubic catheter. This generic type of device includes the introducer, access dilator, and peel-away sheath.

(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 § 876.9.

■ 7. Add § 876.5290 to subpart F to read as follows:

§ 876.5290 Implanted mechanical/hydraulic urinary continence device surgical accessories.

(a) *Identification*. Implanted mechanical/hydraulic urinary continence device surgical accessories are manual devices designed to be used for surgical procedures associated with the implantation of an implanted mechanical/hydraulic urinary continence device. This generic type of device includes the measurement tool or tape, connector assembly tool, tubing plug, incision closing tool, tubing passer, blunt needle, and hemostat shod tubing.

(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 § 876.9.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 8. The authority citation for part 878 continues to read as follows:

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

■ 9. Add § 878.5080 to subpart F to read as follows:

§ 878.5080 Air-handling apparatus accessory.

(a) *Identification*. An air-handling apparatus accessory is a supplementary device that is intended to be used with an air-handling apparatus for a surgical operating room. This device provides an interface between the components of the device or can be used to switch electrical power. This generic type of device includes fittings, adapters, couplers, remote switches, and footswitches.

(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 § 878.9.

PART 886—OPHTHALMIC DEVICES

■ 10. The authority citation for part 886 continues to read as follows:

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

■ 11. Add § 886.4355 to subpart F to read as follows:

§ 886.4355 Corneal inlay inserter handle.

(a) *Identification*. The corneal inlay inserter handle is a hand-held device intended to be used as an accessory to a corneal inlay inserter. The device extends the length of the inlay inserter to aid in delivering the inlay implant.

(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.

Dated: April 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-07290 Filed 4-11-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2019-0024]

RIN 1625-AA00

Safety Zone; Xterra Swim, Intracoastal Waterway; Myrtle Beach, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Atlantic Intracoastal Waterway in Myrtle Beach, South Carolina. This action is necessary to provide for the safety of the swimmers, participant vessels, spectators, and the general public during the swim portion of the Xterra Triathlon. This regulation prohibits non-participant vessels and persons from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from 7 a.m. through 9 a.m. on April 14, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0024 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Justin Heck, Sector Charleston Waterways Management division, Coast Guard; telephone (843) 740-3184, email Justin.c.check@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On January 9, 2019, Go Race Productions notified the Coast Guard that it would be sponsoring the Xterra Swim from 7:30 a.m. to 8:30 a.m. on April 14, 2019. Approximately 200 swimmers are anticipated to participate in the swim portion of the event, which is a 1500-yard course, located on certain waters of the Atlantic Intracoastal Waterway in Myrtle Beach, South Carolina. In response, on March 1, 2019, the Coast Guard published an NPRM titled “Safety Zone, Xterra Swim, Intracoastal Waterway, Myrtle Beach, SC” (84 FR 6994). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this event. During the comment period that ended March 30, 2019, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Charleston (COTP) has determined that potential hazards associated with the large number of participants during the swim will be a safety concern. The purpose of the rule is to ensure the safety of the participants, spectators, the general public, vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published March 1, 2019. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from 7:00 a.m. to 9:00 a.m. on April 14, 2019. The safety zone will cover a portion of the Atlantic Intracoastal Waterway in Myrtle Beach, South Carolina. Approximately 200 swimmers are anticipated to participate in the race. The duration of the zone is intended to ensure the safety of the participants, the general public, vessels and the navigable waters before, during, and after the scheduled 7:30 a.m. to 8:30 a.m. swim. No vessel or person will be permitted to enter, transit through, anchor in or remain within the safety zone without obtaining permission from COTP Charleston or a designated representative. If authorization to enter, transit through, anchor in, or remain within the safety zone is granted by the COTP or a designated representative, all persons and vessels receiving such authorization must comply with the

instructions of the COTP or a designated representative. The Coast Guard will provide notice of the safety zone by local notice to mariners, broadcast notice to mariners, or by on-scene designated representatives.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on: (1) The temporary safety zone will only be enforced for two hours; (2) although persons and vessels may not enter, transit through, anchor in, or remain within the regulated area without authorization from the COTP Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; and, (3) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners, or by on-scene designated representatives.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 received zero comments from the Small Business Administration on this rulemaking. 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

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 rule. 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 person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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). 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.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. 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 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit persons and vessels from entering, transiting through, anchoring in, or remaining within a limited area near Myrtle Beach, SC, on the waters of the Intracoastal Waterway in Myrtle Beach, SC, during a race event lasting two hours. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

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: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07–0024 to read as follows:

§ 165.T07–0024 Safety Zone; Xterra Swim, Myrtle Beach SC.

(a) *Location.* The following is a safety zone: Certain waters of the Atlantic Intracoastal Waterway within the following two points of position and the North shore: 33°45′03″ N, 78°50′47″ W to 33°45′18″ N, 78°50′14″ W, located in Myrtle Beach, South Carolina. All coordinates are North American Datum 1983.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at 843–740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement period.* This rule will be enforced from 7:00 a.m. until 9:00 a.m. on April 14, 2019.

Dated: April 5, 2019.

J.W. Reed,

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

[FR Doc. 2019–07263 Filed 4–11–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0057]

RIN 1625–AA00

Safety Zone; Laguna Madre, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of the Laguna Madre in support of the 2019 Wings over South Texas Air Show. This action is necessary to protect personnel, vessels, and the marine environment from potential hazards during aerobatic maneuvers by high-speed, low-flying airplanes and any navigation hazards associated with the set up within certain waters of Laguna Madre. This action will prohibit persons and vessels from entering the zone unless authorized by the Captain of the Port Corpus Christi (COTP) or a designated representative.

DATES: This rule is effective from 11 a.m. on April 11, 2019 through 5 p.m. on April 14, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2019–0057 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Margaret Brown, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email Margaret.A.Brown@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
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U.S.C. United States Code